



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

October 12, 2016

Mr. Nathan Bass
Plant Manager
Valley Queen Cheese Factory, Inc.
200 E. Railway Avenue
P.O. Box 351
Milbank, SD 57252

SUBJECT: NRC INSPECTION REPORT 999-90001/2016-001 AND NOTICE OF VIOLATION

Dear Mr. Bass:

This letter refers to an unannounced special inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on May 3, 2016 at the Valley Queen Cheese Factory, Inc. located in Milbank, South Dakota. Additionally, communications with your staff and the authorized gauge vendor to obtain additional records and subsequent analysis and review of the information, contributed to in-office reviews lasting through August 24, 2016. The purpose of the inspection was to review the facility's control of a generally licensed device containing cesium-137. The enclosed report presents the results of this inspection. The inspector discussed the preliminary results of this inspection with you during an on-site exit on May 3, 2016. A final exit was conducted telephonically with you on October 6, 2016.

The purpose of this inspection was to examine activities conducted under your general license as they relate to public health and safety, the common defense and security, to confirm compliance with the Commission's rules and regulations, and with the conditions of your general license. Within these areas, the inspection consisted of selected examination of representative records, observations of activities, and interviews with personnel.

Based on the information developed during the inspection, the NRC has determined that four 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's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). These violations include: (1) failure to assure that removal of the generally licensed gauge was performed by an authorized licensee, (2) failure to register the generally licensed gauge and pay the associated fees while it was in your possession, (3) storing a generally licensed gauge not in use for a period exceeding two years, and the failure to assure the shutter was locked in the closed position while it was in storage, and (4) failure to notify the NRC within 30 days of transfer of the gauge. The violations are being cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC during an inspection.

Based on the fact that your facility is no longer in possession of the gauge, the NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved was already adequately addressed during the inspection. Therefore, you are not

required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If you have any questions concerning this matter, please contact Mr. Ray Kellar, P.E. of my staff, at 817-200-1191.

Sincerely,

/RA/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

Docket No. 999-90001
License No. Generally Licensed

Enclosures:

- 1) Notice of Violation
- 2) Inspection Report 99990001/2016-001

Attachment: Supplemental Information

cc w/enclosure:
South Dakota Radiation Control Program Director

NOTICE OF VIOLATION

Valley Queen Cheese Factory, Inc.
Milbank, South Dakota

Docket No. 999-90001
License No. Generally License

During an NRC inspection conducted on May 3, 2016, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 31.5(c)(3)(ii) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall assure that installation, servicing and removal from installation involving radioactive materials, its shielding or containment, are performed by a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities.

Contrary to the above, in February 2013, the general licensee that possessed byproduct material in a device failed to assure that removal from installation involving radioactive materials was performed by a person holding a specific license to perform such activities. Specifically, the Valley Queen Cheese Factory, Inc. personnel removed piping with a fixed gauge containing radioactive material still in place, and placed the gauge/piping into storage until it was transferred to the manufacturer in March of 2016 rather than contracting for the deinstallation service with a licensee specifically licensed to perform this work.

This is a Severity Level IV violation (Section 6.3.d).

- B. 10 CFR 31.5(c)(13)(i) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall register in accordance with 10 CFR 31.5(c)(13)(ii) and (iii), devices containing at least 370 megabecquerels (10 millicuries) of Cs-137.

10 CFR 31(c)(13)(ii) requires, the person in possession to register these devices annually with the Commission and shall pay the fee required by §170.31 of this chapter.

Contrary to the above, between 2000 and 2016, the general licensee possessed byproduct material in a device pursuant to a general license and failed to register the device containing at least 370 megabecquerels (10 millicuries) of Cs-137 annually with the Commission and pay the fee. Specifically, the Valley Queen Cheese Factory, Inc., possessed a Berthold gauge containing 1,000 millicuries of Cs-137 that was not registered with the Commission and failed to pay the required fee.

This is a Severity Level IV violation (Section 6.9.d)

- C. 10 CFR 31.5(c)(15) requires, in part, that any persons who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position.

Contrary to the above, from February 2013 to March 2016, the general licensee possessed a byproduct device that was not in use for longer for 2 years and failed to store the device with the shutter locked in the closed position. Specifically, the Valley Queen Cheese Factory, Inc. placed a gauge into storage in February of 2013 and did not transfer the gauge to the manufacturer until March 15, 2016 a period greater than two years. Discussions with the manufacturer who took possession of the gauge on March 15, 2015, revealed that the gauge was found by the manufacturer with the shutter locked in the open position.

This is a Severity Level IV violation (Section 6.3.d)

- D. 10 CFR 31.5(c)(8)(ii) requires, in part, any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall within 30 days after the transfer of the device to a specific licensee furnish a report to the Director, Office of Nuclear Materials Safety and Safeguards, ATTN: Document Control Desk/GLTS.

Contrary to the above, from March 15, 2016 to May 3, 2016, the general licensee failed to within 30 days after the transfer of a device to a specific licensee furnish a report to the Director, Office of Nuclear Materials Safety and Safeguards. Specifically, Valley Queen Cheese Factory, Inc. failed to report the transfer of the generally licensed gauge after it had been transferred to Berthold on March 15, 2016. As of the date of the inspection on May 3, 2016, a period greater than 30 days, a report had not been filed with the NRC.

This is a Severity Level IV violation (Section 6.3.d)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed in this inspection report, ADAMS accession number (ML16258A467). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 12 day of October 2016

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket: 999-90001

License: Generally Licensed

Report: 999-90001/2016-001

Facility: Valley Queen Cheese Factory, Inc.

Location: 200 E. Railway Avenue
Milbank, SD 57252

Dates: May 3, 2016 through August 24, 2016

Inspector: Martha R. Poston, Health Physicist
Nuclear Materials Safety Branch A

Approved By: Ray L. Kellar, P.E, Chief
Nuclear Materials Safety Branch A

EXECUTIVE SUMMARY

Valley Queen Cheese Factory, Inc.,
NRC Inspection Report 999-90001/2016-001

This was an unannounced special inspection of Valley Queen Cheese Factory, Inc. involving the use of byproduct material in a generally-licensed device for measuring production in its facilities at Milbank, SD. The onsite portion of the inspection was conducted on May 3, 2016, and inspection continued with in-office reviews through July 28, 2016 and additional analysis until August 24, 2016.

Program Overview

- Valley Queen Cheese Factory, Inc. was authorized under a general license issued in accordance with 10 CFR 31.5(a), in part, to acquire, receive, possess, use and transfer byproduct material contained in devices designed and manufactured for the purposes of detecting, measuring, gauging or controlling thickness. Valley Queen Cheese Factory, Inc. was in possession of a single gauge. This gauge was installed as part of the milk evaporator system in early 1982. The source activity was estimated to be 3.7 GBq (1 Ci) at the time of installation. The milk evaporator system was deinstalled by Valley Queen Cheese Factory, Inc. in February of 2013 and the components placed in storage in stainless steel containers located in the loading dock area of the plant. In March of 2016, Valley Queen Cheese Factory, Inc. contracted with Berthold Technologies USA to have the gauge removed from their site as part of a scrap reduction program. This removal was completed by Berthold Technologies USA, a specific license holder authorized to deinstall/remove the gauge on March 16, 2016. Upon removal of this gauge, the licensee is no longer in possession of any byproduct material.

Violations

- Failure to ensure removal or deinstallation of the device was performed by individuals specifically licensed to do so. This was identified as a violation of 10 CFR 31.5(c)(3).
- Failure to annually register the device and pay the associated fee to the U.S. Nuclear Regulatory Commission as required for a device with an activity exceeding 370 Bq of cesium-137. This was identified as a violation of 10 CFR 31.5(c)(13)(i).
- Failure to hold a device for longer than 2 years that is not in use and failure to lock the shutter in a closed position. This was identified as a violation of 10 CFR 31.5(c)(15).
- Failure to provide a report to the NRC related to the transfer of the generally licensed gauge. This was identified as a violation of 10 CFR 31.5(c)(8)(ii).

Dose Estimates

- There is no information available on the methods used by plant staff to dismantle the milk evaporator system nor the number of personnel involved. The stainless steel revac chambers were stored inside a fenced-in area away from locations where site personnel would be working. Thus, the analysis of potential personnel exposure will focus on the

forklift operator responsible for movement of the gauge with associated piping from the revac chamber as described in Section 2.3.

- The estimated dose to the forklift operator at Valley Queen Cheese that moved the gauge is estimated as 26 mrem (whole body), which is less than the annual limit permitted in 10 CFR Part 20 of 100 mrem to members of the general public.

REPORT DETAILS

1. Program Overview

In accordance with 10 CFR 31.5(a), Valley Queen Cheese Factory, Inc. was issued a general license and was authorized to acquire, receive, possess, use and transfer byproduct material contained in devices designed and manufactured for the purposes of detecting, measuring, gauging or controlling thickness. The inspector reviewed records and interviewed licensee personnel.

2. Inspection Findings (87121)

2.1 Overview

Valley Queen Cheese Factory, Inc. was in possession of single fixed gauge (Berthold Model LB7442D). The gauge and detector were installed in early 1982 as part of a milk evaporator system sold to Valley Queen Cheese Factory, Inc. by Wiegand Evaporator. The gauge contained a cesium-137 source with an activity of 1000 mCi at the time of installation. In the installed position the gauge was 14 feet above ground level. The milk evaporator system was removed from the plant by Valley Queen Cheese Factory, Inc. staff in February of 2013 and the components were stored in three stainless steel walk-in containers. These containers were placed in the loading dock parking area. In early 2016, the new plant manager decided to sell the milk evaporator components as scrap metal, so the stainless steel containers were opened and the gauge was located. The new plant manager contacted Berthold Technologies, holder of the sealed source and device register for this gauge, regarding proper transfer and disposal. On March 15, 2016, Berthold Technologies took possession of the gauge and shipped it to their facility in Tennessee.

2.2 Observations and Findings

Once the inspector confirmed that the gauge had been removed from the site and no other gauges or sources of radiation were present onsite, the inspector asked to review records associated with the previously possessed gauge. The licensee was only in possession of the leak test performed by Berthold prior to their shipment of the gauge back to their facility. The licensee indicated that the individual who had been assigned responsibility for the milk evaporator system and the gauge had left the company in 2015, and the remaining managers were not aware of any records associated with the gauge. The plant manager agreed to search for records and make them available to the NRC if they were found. On May 9, 2016, the plant manager confirmed via email that the plant was unable to locate any files or documentation associated with the gauge and detector. The inspector continued to gather information associated with the gauge movement and radiation dose rates from Valley Queen Cheese Factory, Inc. and Berthold Technologies USA through July 28, 2016.

The NRC inspector contacted the NRC staff responsible for managing the Generally Licensed Tracking System (GLTS) database. A search was conducted of the database and no records associated with registration and fees were found for this device or for any device in Milbank, SD.

A literature search was done in ADAMS for the gauge and detector and the distributor (BSI Instruments/Apgee Corporation). These companies are no longer in business or in possession of NRC licenses. In 1996 for the NRC issued an inspection report 030-32518/96-001 dated August 12, 1996 that identified Apgee's failure to "distribute devices with manuals that included written instructions advising customers not to lock the shutter in the open position." Since the installation of the gauge precedes that inspection, this issue might be a reasonable explanation as to why the Valley Queen Cheese Factory did not maintain the appropriate documents or have a true understanding of the hazard associated with the fixed gauge.

Literature on the gauge and detector found on the sealed source and device registration or the Berthold Technologies website indicate the LB7442D device is configured such that the source is contained in a tightly sealed stainless steel capsule. This capsule is mounted in a shielded housing using a source holder. A shutter is provided to close the radiation outlet channel, by rotating a handle and securing the handle with a padlock. The source is mounted in the middle of the cavity in the shield, approximately 8" from the shutter controls and 4" from the aperture opening. The angle of the aperture is 11°, creating a point source. When installed the detector is across from the source and the gauge and its detector are mounted on plates on each side of the pipe.

Based on the result of the above efforts the following violations were identified.

Violation of 10 CFR 31.5(c)(3)(ii)

10 CFR 31.5(c)(3)(ii) requires, in part, that any person who acquires, received, possess, uses or transfers byproduct material in a device pursuant to a general license, shall ensure that tests required by paragraph (c)(2) of this section and other testing, installation, service and removal from installation are performed by persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to perform such activities.

Based on the above information, the inspector determined that Valley Queen Cheese Factory, Inc. failed to ensure that removal of the device from installation was performed by an organization specifically licensed to perform such activities. Rather, Valley Queen Cheese Factory, Inc. personnel removed the piping and the gauge from service in February of 2013 and placed the gauge into storage until a specifically licensed organization removed the gauge from the piping the gauge was attached to in March of 2016.

Violation of 10 CFR 31.5(c)(13)(i)

10 CFR 31.5(c)(13)(i) requires, in part, that any person who acquires, possess, uses or transfers byproduct material in a device pursuant to a general license...shall register in accordance with the requirements of (c)(13)(ii) and (iii) of this section, any device containing at least 370 MBq (10 millicuries) of cesium-137.

Based on an exhaustive search of the GLTS system, the inspector determined that Valley Queen Cheese Factory, Inc. failed to register the device. The requirements of 10 CFR 31.5(c)(13)(ii) specify that this registration shall be annually and the associated fees should be paid. The requirement to register the device went into effect in December 2000, therefore the licensee failed to register the device from 2000 till it was transferred in March of 2016.

Violation of 10 CFR 31.5(c)(15)

10 CFR 31.5(c)(15) requires, in part, that any person who acquires, possess, uses or transfers byproduct material in a device pursuant to a general license may not hold devices that are not in use for longer than two years. If the devices with shutters are not being used, the shutter must be in the locked in the closed position.

Based on the above, the inspector determined that Valley Queen Cheese Factory, Inc. maintained a gauge in storage from February 2013 to March 2016, a period greater than two years and that the gauge was not stored with the shutter locked in the closed position.

Violation of 10 CFR 31.5(c)(8)(ii)

10 CFR 31.5(c)(8)(ii) requires, in part, that that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section: shall within 30 days after transfer of a device to a specific license furnish a report to the Director, Office of Nuclear Materials Safety and Safeguards.

At the time of the inspection, May 3, 2016, it was determined that Valley Queen Cheese Factory, Inc. had not furnished a report to the NRC for the transfer that occurred March 15, 2016.

2.3 Dose Estimates

There is no information available on the methods used by plant staff to dismantle the milk evaporator system nor the number of personnel involved. The stainless steel revac chambers were stored inside a fenced-in area away from locations where site personnel would be working. Thus, the analysis of potential personnel exposure will focus on the forklift operator responsible for movement of the gauge with associated piping from the revac chamber as described below.

Discussions with plant management yielded the following information associated with the gauge. The gauge and its associated detector were still attached to the steel pipe that it had been installed on when the plant dismantled the milk evaporator system. The pipe extended three feet in each direction from the source and its detector, and one of the ends was capped to a pipe bend connection. The pipe, gauge and detector were secured to a pallet and placed into one of three stainless steel walk-in containers (revac chamber). The licensee could not provide any information on which container the gauge had been stored in. The stainless steel revac chambers were stored in the loading dock parking area from February 2013 till March 2016. Once the arrangements were made with Berthold for the gauge and detector to be transferred to Berthold Technologies USA, the pallet with the piping, gauge and detector, was removed from the stainless steel revac chamber and placed in a materials storage area approximately 10 feet from an exterior wall. The movement is estimated by the licensee to have taken less than 10 minutes to accomplish. Management was not aware if the shutter was opened or closed. It was assumed by the inspector to have been stored with the shutter opened, as manufacturer literature indicates a key is required to move the shutter to the closed position.

The inspector contacted the Radiation Safety Officer at Berthold Technologies, USA to obtain information associated with radiation dose rates for the gauge and source (500 mCi at the time of receipt by Berthold). These dose rates do not take into consideration any shielding or dose attenuation that might have been provided by the pipe or the detector that were still in place while the gauge was in storage or during the movement and would be an upper bound estimate for actual dose rates. The information provided by Berthold indicated the following dose rates: 2.1 R/hr on contact, 863 mR/hr at 30 cm, and 155 mR/hr at one meter. Using the latter number, and since we are dealing with a gamma ray in air, a conversion factor is not needed to convert mR/hr to mrem/hr, a dose estimate was determined for the forklift operator who was responsible for moving the gauge and its piping from the stainless steel storage container. It is assumed that the forklift operator would be the individual closest to the gauge during the movement of the gauge to and from the stainless steel storage container.

The licensee estimated that the movement took ten minutes. It is assumed that the distance from the gauge to the operator in the cab is one meter. It is also assumed that due to ability of the forklift to pick up the pallet containing the gauge the dose would be to the whole body rather than extremities.

$$\begin{aligned} [155 \text{ mrem/hr}] / [60 \text{ min/hr}] &= 2.58 \text{ mrem/min} \\ [2.58 \text{ mrem/min}] \times [10 \text{ mins}] &= 26 \text{ mrem (whole body)} \end{aligned}$$

Thus the estimated exposure to the fork lift operator is 26 mrem (whole body), which is less than the NRC limit of 100 mrem/year allowed by 10 CFR Part 20 for members of the public.

3. Summary

There are no corrective actions required by the general licensee, as it no longer possesses the gauge.

There is insufficient information available to determine potential dose rates associated with the removal of the piping and gauge from the evaporator system and storage in the stainless steel storage containers. The estimated radiological dose associated with the fork lift operator movement of the gauge for disposal is less than the annual exposure limits to members of the public of 100 mrem/year.

4. Exit Meeting Summary

A preliminary exit meeting was conducted with the Valley Queen Cheese Factory, Inc. Plant Manager, Mr. Nathan Bass on May 3, 2016, at the conclusion of the onsite inspection. A final exit briefing was held telephonically with Mr. Bass on October 6, 2016. The licensee acknowledged the inspector's findings. No proprietary information was discussed.

LIST OF INDIVIDUALS CONTACTED

Nathan Bass, Plant Manager, Valley Queen Cheese Factory, Inc.
Lance Johnson, Vice President, Manufacturing, Valley Queen Cheese Factory, Inc.
Mark Leddy, Chief Executive Officer, Valley Queen Cheese Factory, Inc.

INSPECTION PROCEDURES USED

87124 Fixed and Portable Gauge Programs

ITEMS OPENED, CLOSED AND DISCUSSED

Opened

99990001/2016001-01	VIO	Failure to ensure that removal or deinstallation of the device was performed by individuals specifically licensed to do so. This was identified as a violation of 10 CFR 31.5(c)(3).
99990001/2016001-02	VIO	Failure to annually register the device and pay the associated fee to the NRC as required for a device with an activity exceeding 370 Bq of cesium-137. This was identified as a violation of 10 CFR 31.5(c)(13)(i).
99990001/2016001-03	VIO	Storage of an unused device for a period of greater than two years and failure to ensure a device was stored with the shutter in the closed position. This was identified as a violation of 10 CFR 31.59(c)(15).
9990001/2016001-04	VIO	Failure to furnish a report within 30 days after the transfer of a generally licensed device. This was identified as a violation of 10 CFR 31.5(c)(8)(ii).

Closed

None

required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If you have any questions concerning this matter, please contact Mr. Ray Kellar, P.E. of my staff, at 817-200-1191.

Sincerely,

/RA/

Mark R. Shaffer, Director
 Division of Nuclear Materials Safety

Docket No. 999-90001
 License No. Generally Licensed

Enclosures:

- 1) Notice of Violation
- 2) Inspection Report 99990001/2016-001

Attachment: Supplemental Information

cc w/enclosure:
 South Dakota Radiation Control Program Director

Distribution

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