

# **SAFETY EVALUATION REPORT**

**Docket No. 71-9355  
Model No. 435-B  
Certificate of Compliance No. 9355  
Revision No. 2**

**This page was left intentionally blank.**

# TABLE OF CONTENTS

	Page
<b>SUMMARY .....</b>	<b>1</b>
<b>1.0 GENERAL INFORMATION .....</b>	<b>- 2 -</b>
1.1 Packaging .....	- 2 -
1.2 Drawings .....	- 2 -
1.3 Contents.....	- 2 -
<b>2.0 STRUCTURAL EVALUATION .....</b>	<b>- 3 -</b>
2.1 Description of Structural Design.....	- 3 -
2.2 Materials Evaluation.....	- 3 -
2.3 Normal Conditions of Transport and Hypothetical Accident Conditions.....	- 3 -
2.4 Evaluation Findings.....	- 4 -
<b>3.0 Thermal Evaluation .....</b>	<b>- 4 -</b>
3.1 Description of Thermal Design.....	- 4 -
3.2 General Considerations for Thermal Evaluation .....	- 5 -
3.3 Thermal Evaluation under NCT.....	- 5 -
3.4 Thermal Evaluation under HAC .....	- 6 -
3.5 Evaluation Findings.....	- 7 -
<b>4.0 Containment Evaluation .....</b>	<b>- 7 -</b>
4.1 Description of the Containment System.....	- 7 -
4.2 Containment under Normal Conditions of Transport.....	- 8 -
4.3 Containment under Hypothetical Accident Conditions .....	- 8 -
4.6 Evaluation Findings.....	- 9 -
<b>7.0 PACKAGE OPERATIONS .....</b>	<b>- 9 -</b>
<b>8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW .....</b>	<b>- 10 -</b>
<b>9.0 QUALITY ASSURANCE.....</b>	<b>- 10 -</b>
<b>CONDITIONS .....</b>	<b>- 10 -</b>
<b>CONCLUSIONS .....</b>	<b>- 11 -</b>

**This page was left intentionally blank.**

## SAFETY EVALUATION REPORT

Docket No. 71-9355  
Model No. 435-B  
Certificate of Compliance No. 9355  
Revision No. 2

### SUMMARY

The U.S. Department of Energy, National Nuclear Security Administration (NNSA or the applicant), requested a revision to the Model No. 435-B packaging certificate of compliance (CoC) by application dated April 27, 2017 (Agencywide Document Access and Management System (ADAMS) Accession No. ML17138A026), as supplemented on November 9, 2017 (ADAMS Accession No. ML17335A008).

In summary, the applicant proposed the following revisions to the Model No. 435-B package:

- 1) use bolts in lieu of adhesive to attach neoprene to the lodgment,
- 2) change the standards for the inner container (IC) bolts and washers;
- 3) use of lock washers to secure bolts;
- 4) remove the use of thin (1/8-inch thick) neoprene;
- 5) add breather vents to the IC lid;
- 6) add a new case to the thermal analysis to evaluate the thermal effect of using metallic dunnage with a shielded device in the IC;
- 7) add Section 3.4.3.5 to the thermal analysis to document the evaluation of the thermal decomposition response, under hypothetical accident conditions, of non-metallic materials that may be transported within containment;
- 8) revise operating procedures to allow the slings used to lift the shielded device during loading to be left in the IC for use in unloading; and
- 9) modifications to drawings to reflect changes identified during fabrication of the packaging.

The applicant designed the packaging with a base; a bell cover; an internal lodgment which supports the Long Term Storage Shield (LTSS); an IC which supports shielded devices; and two internal impact limiters. Unless noted otherwise, the applicant fabricated all elements from Type 304 stainless steel in conformance with ASTM A240. The applicant designed the package to be transported singly, with its longitudinal axis vertical, by road, by air, or by waterway in non-exclusive use. The applicant designed the Model No. 435-B package to provide a leaktight containment to preclude a release of the radioactive contents that might exceed that allowed by the regulations in Title 10 of the *Code of Federal Regulations* (CFR) Part 71, under all normal conditions of transport (NCT) and hypothetical accident conditions (HAC).

The NRC staff (the staff) reviewed the application, including relevant supplemental information, using the guidance in NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material." Based on the statements and representations in the application, as supplemented, and the conditions listed below, the staff concludes that the package meets the requirements of 10 CFR Part 71.

## **1.0 GENERAL INFORMATION**

### **1.1 Packaging**

Section 1.2.1 of the safety analysis report (SAR) provided a detailed description of the packaging. Section 1.1, "Packaging," of the safety evaluation report (SER) for revision 0 of the CoC of the Model No. 435-B (ADAMS Accession No. ML14199A693) included a brief description of the structural protection features for the Model No. 435-B package, and identified the following principal structural components:

- a. Lower Body Assembly (Base)
- b. Upper Body Assembly (Bell)
- c. Lodgment/LTSS
- d. Inner Container/Shielded Device
- e. Internal Impact Limiters

As discussed above in the "Summary" section of this SER, the applicant requested changes to the standards used to designate bolts and washers for the IC, the inclusion of additional lock washers to secure bolts, and the use of fasteners to secure the neoprene cushion in contact with the lodgment in lieu of adhesive.

### **1.2 Drawings**

The applicant constructed the packaging in accordance with the following AREVA Federal Services LLC drawings:

- a. 1916-01-01-SAR, "435-B Package Assembly SAR Drawing," sheets 1-7, Revision 6
- b. 1916-01-02-SAR, "435-B LTSS Lodgment SAR Drawing," sheets 1-2, Revision 4
- c. 1916-01-03-SAR, "435-B Inner Container SAR Drawing," sheets 1-2, Revision 4

The applicant revised all the drawings to reflect the changes related to this licensing action request. The staff reviewed the drawings and found they adequately represented the package. The drawings included dimensions, package markings, materials of construction, and the codes and standards used to design the package.

### **1.3 Contents**

The applicant neither requested to add nor requested to remove radioactive contents from the Model No. 435-B. However, the applicant requested to add the items in Table 3.4-4, "Non-metallic Contents Materials," of the SAR as allowed contents.

The staff reviewed the contents description and concludes it meets the requirements of 10 CFR Part 71.

## **2.0 STRUCTURAL EVALUATION**

The purpose of this evaluation is to verify that the proposed changes to the Model No. 435-B transport package design provide adequate protection against loss or dispersal of radioactive contents and to verify that the package design meets the requirements of 10 CFR Part 71 under NCT and HAC.

### **2.1 Description of Structural Design**

SAR Section 1.2.1 identified the principal structural components of the Model No. 435-B package as follows:

- a. Lower Body Assembly (Base)
- b. Upper Body Assembly (Bell)
- c. Lodgment/LTSS
- d. Inner Container/Shielded Device
- e. Internal Impact Limiters

SAR Section 1.2.1 and Section 1.1, "Packaging," of the SER for CoC Revision 0 of the Model No. 435-B included a description of the structural protection features for the Model No. 435-B package.

#### **2.1.2 Design Criteria**

The design criteria for the Model 435-B package remained unchanged.

### **2.2 Materials Evaluation**

The applicant requested to use bronze bolts in lieu of stainless steel bolts to secure the LTSS to the LTSS lodgement. This change brought dissimilar metals into contact which raised the possibility of galvanic corrosion. Staff evaluated this change and determined that the possibility of galvanic corrosion was unlikely because water, a necessary component of galvanic corrosion, is only present as water vapor in air during transport. Staff determined that this amount of water was not sufficient to cause failure of the bolts during transport.

The applicant added SAR Section 3.4.3.5 to document the evaluation of the thermal decomposition response under HAC of non-metallic packaging materials that may be transported within containment. The applicant demonstrated that the quantity of these non-metallic packaging materials was insufficient to over-pressurize the package during the HAC fire event. Staff also confirmed that these non-metallic packaging materials have been previously evaluated, accepted and used without incident in radioactive material packages transporting similar payload materials. Therefore, the staff's review focused only on the potential for their degradation to affect the important to safety (ITS) containment boundary. Section 4.0 of the SER includes the staff's materials evaluation related to this change.

### **2.3 Normal Conditions of Transport and Hypothetical Accident Conditions**

For the Model No. 435-B design, staff evaluated in section 2.2 of this SER the performance of the materials associated with the applicant proposed changes described in the "Summary" section of this SER. Regarding the request to update the standards used for the six 1-8 UNC bolts and washers, the staff determined that the changes will not adversely affect the

performance of the package as the bolts will continue to provide the same or greater level of structural performance. The applicant also requested to use mechanical fasteners (1/4-inch diameter stainless steel flat head screws) in lieu of adhesive to attach the 1/2 inch neoprene pad in the LTSS lodgment. The applicant identified the neoprene pad as not ITS. Therefore, the staff finds that the proposed changes requested by the applicant will not adversely affect the structural performance of the package under NCT and HAC.

In addition, the applicant requested to replace rubber tipped stainless steel bolts in the toggle clamps used to secure the LTSS with bare bronze bolts. The applicant stated that the toggle bolts minimized vibration of the LTSS during NCT and that the toggle bolts themselves perform no specific safety function since they act as dunnage. The applicant explained that the rubber tips help to prevent marring of the LTSS finish. The applicant stated that the lodgment structure itself primarily handles the impact loads and that the lodgment fully controls the LTSS under NCT. The applicant noted that the toggle bolts used in prototype drop testing for package qualification, which were made of bare steel, bent and became unlatched during drop testing. Nevertheless, the bare steel toggle bolts caused minimal damage to the LTSS (ADAMS Accession No. ML17335A008). Because the toggle clamps do not have a safety function, and because the applicant used similar materials of construction (bronze vs steel), staff finds that the bronze toggle bolts should perform adequately under both NCT and HAC conditions.

## **2.4 Evaluation Findings**

The staff reviewed documentation to confirm that statements made by the applicant were accurate and within acceptable engineering practices. Based on a review of the statements, representations, and supplemental information provided, the staff concludes that the structural design has been adequately described and evaluated and that the package has adequate structural integrity to meet the requirements of 10 CFR Part 71.

## **3.0 THERMAL EVALUATION**

The purpose of this thermal evaluation is to verify that the proposed changes to the Model No. 435-B design:

1. provide adequate protection against the thermal tests specified in 10 CFR Part 71, and
2. meet the thermal performance requirements of 10 CFR Part 71 under NCT and HAC.

Regulations applicable to the thermal review include 10 CFR 71.31, 71.33, 71.35, 71.43, 71.51, 71.71, and 71.73. The following sections summarize the staff's thermal evaluation.

### **3.1 Description of Thermal Design**

The "Summary" section of this SER briefly described the proposed changes to the Model No. 435-B design. The following changes affected the thermal design:

- a. a new thermal analysis case to evaluate the thermal effect of using metallic dunnage with a shielded device in the IC,

- b. a new thermal analysis section (Section 3.4.3.5) to document an evaluation of the thermal decomposition response of non-metallic materials within containment under HAC.

### **3.2 General Considerations for Thermal Evaluation**

The applicant noted in SAR Section 3.2.1, "Material Properties," that the dunnage/blocking used for the shielded devices is analyzed as either being entirely polyurethane foam or a metallic structure.

The applicant stated in SAR Section 3.2.2, "Component Specifications," that the neoprene pad, which is attached to the lodgment to provide a cushion for the LTSS, has a working temperature range between -40°F and approximately 200°F. The applicant indicated that, although neoprene does not melt, it undergoes thermal-decomposition at a temperature of 500°F. The applicant stated that maintaining the neoprene below 500°F will prevent significant off-gassing and eliminate any possibility for auto-ignition of the material.

The applicant stated in SAR Section 3.3.1, "Heat and Cold," that the Thermal Desktop and SINDA/FLUINT codes were used to model the package thermal performance under NCT and HAC.

### **3.3 Thermal Evaluation under NCT**

#### **3.3.1 Heat and Cold**

The applicant presented the cold condition results in SAR Table 3.3-2 for a shielded device with a 30 W decay heat load supported by polyurethane foam dunnage. Because the applicant expected the same thermal temperature gradients between adjacent components when a shielded device is supported by metallic dunnage as compared to a shielded device supported with polyurethane foam dunnage, the applicant did not perform additional cold condition thermal analyses. The applicant expected the same thermal temperature gradients because both types of dunnage experienced the same decay heat load. Staff finds this acceptable because the temperatures presented in Table 3.3-2 for NCT cold conditions are within the operating temperatures for all package components.

#### **3.3.2 Maximum Temperatures and Normal Operating Pressure**

The applicant added a thermal analysis of the shielded device payload supported by metallic dunnage in SAR Section 3.3, "Thermal Evaluation for Normal Conditions of Transport," and compared the results with those from the previous analysis of the shielded device supported by polyurethane foam (SAR Table 3.3-2). The applicant noted in SAR Section 3.3 that the most restrictive case for heat transfer between the shielded device and the IC is the shielded device supported by polyurethane. The case of the shielded device supported by metallic dunnage proved to be a less-restrictive configuration for heat transfer because of increased convection and radiation surface areas between the IC and the shielded device. The applicant also noted that the polyurethane foam dunnage provided the worst conditions for gas generation.

The staff reviewed SAR Section 3.3 for the maximum and minimum component temperatures under hot and cold conditions. Although other packaging temperatures are bounding when the shielded device is supported by polyurethane foam dunnage, the maximum temperatures of the top thermal shield, the upper internal impact limiter, the upper torispherical head, and accessible

surfaces are bounding when the shielded device is supported by metallic dunnage. The staff finds the NCT thermal evaluations for the shielded device supported by metallic dunnage acceptable because all packaging component temperatures are below their allowable NCT limits in compliance with 10 CFR 71.71.

### **3.4 Thermal Evaluation under HAC**

#### **3.4.1. Initial Conditions and Fire Test Conditions**

The applicant evaluated two HAC configurations as described in SAR Section 3.4.3.3, "Side Drop Damage with Shielded Device Payload": one with polyurethane foam dunnage and one with metallic dunnage. For the polyurethane model, the applicant centered the shielded device in the IC, and used the maximum amount of polyurethane foam permitted. This configuration analyzed the worst case insulation for the shielded device decay heat and maximized the gas generation during the HAC fire event. For the metallic dunnage model, the applicant placed the shielded device in contact with the IC to maximize temperatures in the shielded device.

#### **3.4.2. Maximum Temperatures**

The applicant presented the HAC event initial conditions in SAR Section 3.4.1, "Initial Conditions," and stated in SAR Section 3.4.3.3.2, "Side Drop Damage with Shielded Device Payload and Metallic Dunnage," that the shielded device is placed in contact with the IC wall after a HAC side drop and puncture damage scenario to the thermal shield. The applicant used this configuration to maximize heat transfer from the fire into the device to generate the maximum device temperatures. The applicant added a thermal analysis of the shielded device supported by metallic dunnage in SAR Section 3.4 and compared the results with those from the previous analysis of the shielded device supported by polyurethane foam. The applicant provided the HAC temperatures for side drop damage with a shielded device in SAR Table 3.4-3.

The staff reviewed the HAC initial conditions, the damage from a side drop accident to a package loaded with a shielded device and metallic dunnage, and temperatures shown in SAR Table 3.4-3. Although other packaging temperatures are bounding when the shielded device is supported by polyurethane foam dunnage, the maximum temperatures of the sealed source capsule, the shielded device, the IC cylindrical wall, the top thermal shield, and the impact limiter shell are bounding when the shielded device is supported by metallic dunnage. The staff finds the HAC thermal evaluations of the shielded device supported by metallic dunnage acceptable because all peak packaging component temperatures are below their allowable HAC limits in compliance with 10 CFR 71.73.

#### **3.4.3 Maximum Pressures**

The applicant stated in SAR Section 3.4.3.4, "Maximum HAC Pressures," that the maximum HAC pressure for the package with a shielded device payload and metallic dunnage is bounded by the LTSS payload pressure of 22.9 psia (8.2 psig) because the peak bulk average cavity gas temperature of 311°F for the case of the shielded device payload with metallic dunnage is lower than 366°F for the case of the LTSS with polyurethane dunnage. In addition, the applicant stated that there is no gas generation from either the metallic dunnage or other organics inside the containment.

The staff reviewed SAR Section 3.4.3.4 and confirmed that the package cavity pressure only rises due to ideal gas expansion with the shielded device payload and metallic dunnage. The staff also confirmed that the maximum HAC pressure for the shielded device payload with metallic dunnage is bounded by the HAC pressure of the LTSS payload. In addition, staff confirmed that there is no gas generation with the shielded device payload and metallic dunnage.

#### **3.4.4 Non-Metallic Contents Materials under HAC**

The applicant presented the temperatures of non-metallic contents materials in SAR Section 3.4.3.5, "Behavior of Non-Metallic Contents Materials under HAC," and SAR Table 3.4-4. The applicant stated that there is significant safety margin for each non-metallic material temperature limit as shown in SAR Table 3.4-4, and that gas generation from thermal decomposition of these materials did not occur in the HAC fire event. As discussed in Section 4.3 of this SER, the staff confirmed that gas generation from the thermal decomposition of these materials will not occur in the HAC fire event because of a significant safety margin for each non-metallic material within the 435-B package.

#### **3.5 Evaluation Findings**

Based on a review of the statements and representations in the application, the staff concludes that the proposed changes to the Model No. 435-B package thermal design have been adequately described and evaluated, and that the package meets the thermal requirements of 10 CFR Part 71.

### **4.0 CONTAINMENT EVALUATION**

The purpose of the containment evaluation is to:

1. confirm that the proposed changes to the Model No. 435-B package meet the requirements for the containment and
2. ensure that the applicant adequately described and evaluated the containment design under NCT and HAC as required in 10 CFR Part 71.

The following sections summarize the staff's containment evaluation.

#### **4.1 Description of the Containment System**

The applicant designed the Model No. 435-B package as a type B package with a leakage rate of less than  $1.0 \times 10^{-7}$  ref-cm<sup>3</sup>/sec per ANSI N14.5. SAR Section 4.1.1, "Containment Boundary," identified the vent port as the only containment penetration. The applicant utilized a containment O-ring fabricated from a butyl elastomer compound which is suitable for continuous use between -65°F and 250°F (-54°C ~ 121°C).

For all containment boundary welds, the applicant utilized full penetration welds which were both radiographically inspected and liquid penetrant inspected to ensure structural and containment integrity in accordance with Subsection NB, Article NB-5000 of the ASME Code as described in SAR Section 4.1.4, "Welds." To ensure that internal pressure would not detach the

package closure bolts under NCT and HAC events, the applicant specified that the package closure lid bolts be tightened to  $300 \pm 30$  ft-lb.

The staff reviewed the application and determined that the Model No. 435-B package containment boundary remains unchanged and that the changes proposed in this revision do not affect the previous containment system design findings.

#### **4.2 Containment under Normal Conditions of Transport**

The staff reviewed the containment evaluation described in SAR Section 4.2, "Containment Under Normal Conditions of Transport," and determined that the changes proposed in this revision do not affect the previous containment findings under NCT. Therefore, staff finds that the Model No. 435-B package remains leaktight per the definition of ANSI N14.5 with no release of radioactive material under NCT tests described in 10 CFR 71.71.

#### **4.3 Containment under Hypothetical Accident Conditions**

The staff reviewed the containment evaluation described in SAR Section 4.3, "Containment Under Hypothetical Accident Conditions," as well as SAR Section 3.4.3.5, to determine if the proposed changes affect the Model No. 435-B package containment boundary. The applicant added SAR Section 3.4.3.5 to document an evaluation of the thermal decomposition response under HAC of non-metallic packaging materials that may be transported within the containment boundary.

Table 3.4-4, "Non-metallic Contents Materials," of the application listed the non-metallic packaging materials, their locations and their temperature limits. The applicant added this section to demonstrate that material decomposition, including outgassing, would not adversely stress the containment boundary. The staff noted that the non-metallic packaging components within the containment boundary are not ITS. Therefore, the staff's review focused only on how their degradation could potentially affect the ITS containment boundary components.

The staff evaluated the HAC temperature limits and reviewed relevant non-metallic material decomposition references. Staff noted that the reported HAC temperatures would neither cause gas generation nor stress the containment boundary. Therefore, the staff finds that there is reasonable assurance that the Model No. 435-B package remains leaktight per the definition of ANSI N14.5 with no release of radioactive material under the HAC tests described in 10 CFR 71.73.

#### **4.4 Leakage Rate Tests for Type B Package**

The applicant leak tested the Model No. 435-B package containment boundary during fabrication, as described in SAR Section 8.1.4, "Fabrication Leakage rate tests," consistent with the guidelines of Section 7.3 of ANSI N14.5. The leakage rate test verified that the package leakage rate was less than  $1 \times 10^{-7}$  ref-cm<sup>3</sup>/sec.

The applicant stated that the Model No. 435-B package containment O-ring seal and the vent port sealing washer will be leakage rate tested in the 12-month period prior to shipment, at the time of damaged containment seal replacement or after sealing surface repair as described in SAR Section 8.2.2, "Maintenance/Periodic Leakage Rate Tests." After reviewing the maintenance/periodic leakage rate tests, staff determined that they are consistent with the

guidelines of Section 7.4 of ANSI N14.5 and that the leakage rate test verifies the integrity of the containment seals to a leakage rate less than  $1 \times 10^{-7}$  ref-cm<sup>3</sup>/sec.

The applicant stated that the containment O-ring seal and the vent port sealing washer are leakage rate tested prior to shipment of the loaded package, per SAR Section 7.4, "Preshipment Leakage Rate test." After reviewing the pre-shipment leakage rate tests, staff determined that they are consistent with the guidelines of Section 7.6 of ANSI N14.5, and that the leakage rate test verifies the integrity of the package to a leakage rate less than  $1 \times 10^{-3}$  ref-cm<sup>3</sup>/sec.

The staff reviewed the leakage rate tests described in SAR Section 4.4, "Leakage Rate Tests for Type B Package," and determined that the proposed changes in this revision do not affect the fabrication, maintenance, periodic, and pre-shipment leakage rate tests.

#### **4.5 ITS Category C Components**

The applicant updated the ITS Categorization Table in Chapter 9, "Quality Assurance," to include the addition of breather vents and fasteners as ITS category C components.

The staff reviewed the containment boundary description in SAR Section 4.1, "Description of the Containment System," and referred to NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety." The staff finds the addition of both the breather vents and the fasteners as ITS category C components acceptable as they are not containment boundary components, and they have only a minor impact on containment performance.

#### **4.6 Evaluation Findings**

Based on review of the statements and representations in the Amendment application, the staff concludes that the proposed changes have no impact to the containment and that the package design still meets the containment requirements of 10 CFR Part 71.

### **5.0 SHIELDING REVIEW**

The changes requested by the applicant did not impact the previous shielding review findings. Therefore, staff did not perform a shielding review.

### **6.0 CRITICALITY REVIEW**

The changes requested by the applicant did not impact the previous criticality review findings. Therefore, the staff did not perform a criticality review.

### **7.0 PACKAGE OPERATIONS**

The purpose of this evaluation is to verify that changes to the operating controls and procedures of the Model No. 435-B transport package meet the requirements of 10 CFR Part 71. The applicant revised the operating instructions to allow:

1. visual inspections of package components at any time during loading operations,
2. loading of neoprene bumpers attached to dunnage and specify the minimum temperature requirements for paint on dunnage,
3. shielded device lifting slings to remain in the IC for unloading operations, and
4. shielded devices and dunnage to be assembled and loaded as a unit.

In addition, the applicant revised the operating instructions to ensure package users:

1. visually inspect O-rings if removed and repair O-rings, if necessary, after removal
2. verify the paint on dunnage can withstand 500°F,
3. remove shielded device components which neither act as shielding for the shielded device nor assist with the shielded device performance,
4. clearly understand the vent port removal process for both the LTSS and the IC, and
5. clearly understand the bolt installation requirements after removing contents from both the LTSS and the IC

After reviewing the statements and representations in the application, the staff concludes that the operating procedures meet the requirements of 10 CFR Part 71 and that these procedures are adequate to assure the package will be operated in a manner consistent with its evaluation for approval.

## **8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW**

Based on review of the statements and representations in the application, the staff concludes that the acceptance tests for the packaging meet the requirements of 10 CFR Part 71, and that the maintenance program is adequate to assure packaging performance during its service life.

## **9.0 QUALITY ASSURANCE**

The applicant changed the Quality Assurance (QA) chapter to update the ITS Categorization table (Table 9.2-2 of the application). The applicant made the change to add breather vents and fasteners as ITS category C components. The staff evaluated the change in Section 4.5 of this SER. The staff concluded that this change does not impact the previous QA program description evaluation.

## **CONDITIONS**

The certificate of compliance includes the following condition(s) of approval:

Condition No. 3.(b), "Title and Identification of Report or Application," includes the date of the consolidated application for the Model No. 435-B.

Condition No. 5.(a)(3), "Drawings," contains the latest revision of the licensing drawings.

The "References" section contains the application submitted on April 27, 2017, and the relevant supplements provided as part of the review process of this licensing action.

## **CONCLUSIONS**

Based on the statements and representations contained in the application, as supplemented, and the conditions listed above, the staff concludes that the design has been adequately described and evaluated, and that the Model No. 435-B package meets the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9355, Revision No. 2,  
on 1/26/18.