

1 DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

2
3 TOPICAL REPORT MIPS-PP-QA-14

4
5 “MEDICAL ISOPTOPE PRODUCTION SYSTEM

6
7 QUALITY ASSURANCE PROGRAM DESCRIPTION”

8
9 BACOCK & WILCOX TECHNICAL SERVICES GROUP, INC.

10
11 PROJECT NO. 766

12
13 1.0 INTRODUCTION AND BACKGROUND

14
15 By letter dated June 4, 2010 (Reference 1), as supplemented by letter dated October 18, 2010,
16 (Reference 2), in response to the U.S. Nuclear Regulatory Commission (NRC) staff's requests
17 for additional information (RAIs) (Reference 3), Babcock & Wilcox Technical Services Group,
18 Inc. (B&W) submitted its Medical Isotope Production System (MIPS) Quality Assurance
19 Program Description Topical Report, MIPS-PP-QA-14, (hereafter referred to as the Quality
20 Assurance Topical Report (QATR)) for NRC review and acceptance in accordance with the
21 provisions of Section 50.34(a)(7) of Part 50 of Title 10 of the *Code of Federal Regulations*
22 (10 CFR).
23

24 2.0 REGULATORY EVALUATION

25
26 Based upon a determination by the NRC staff, B&W's facility will be licensed under the
27 Commission's regulatory requirements related to quality assurance (QA) programs set forth in
28 10 CFR 50.34(a)(7), as a production and utilization facility, classified as a non-power reactor,
29 and require both construction and operating authorization. This regulation requires a
30 description of the QA program to be applied to the design, fabrication, construction, and testing
31 of the structures, systems, and components (SSCs) of the facility. The NRC reviews the
32 proposed QATR for acceptability to ensure the applicable requirements of Appendix B to
33 10 CFR Part 50 will be satisfied.
34

35 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing
36 Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction, and
37 operation of a facility's SSCs. The pertinent requirements of Appendix B to 10 CFR Part 50
38 apply to all activities affecting the safety-related functions of those SSCs and include designing,
39 purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting,
40 testing, operating, maintaining, repairing, refueling, and modifying.

ENCLOSURE

1 3.0 TECHNICAL EVALUATION

2
3 3.1 Background

4
5 The proposed QATR was developed with the purpose of meeting NUREG-1537, "Guidelines for
6 Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1,
7 "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria,"
8 Section 12.9, "Quality Assurance."
9

10 The proposed QATR is organized into 18 basic sections corresponding to the quality
11 requirements delineated in Appendix B to 10 CFR Part 50 and is responsive to both
12 Appendix B, as applicable, and the regulatory guidance set forth in Regulatory Guide 2.5,
13 "Quality Assurance Program Requirements for Research Reactors," Revision 1. Regulatory
14 Guide 2.5 endorses American National Standards Institute/American Nuclear Society
15 (ANSI/ANS) 15.8, "Quality Assurance Program Requirements for Research Reactors."
16

17 3.2 Evaluation

18
19 The NRC staff evaluated the adequacy of the QATR in describing how the requirements of
20 Appendix B to 10 CFR Part 50 will be satisfied. The format, content, and acceptance criteria of
21 the QATR were evaluated in accordance with the guidance of NUREG-1537, Parts 1 and 2,
22 Section 12.9, which provides a basis for NRC staff review of QA programs based on ANSI/ANS
23 15.8. The acceptability of the level of detail provided by the QATR is determined, in part, by its
24 adequacy in addressing the acceptance criteria of NUREG-1537, Parts 1 and 2, Section 12.9.
25

26 3.2.1 Format and Content of the QATR

27
28 The format used for the following evaluation follows the sequence of the 18 criteria of
29 Appendix B and corresponding provisions of ANSI/ANS 15.8. The content of the QATR
30 provides guidance for establishing a top-level policy document that defines the quality
31 requirements and assigns major functional responsibilities. The B&W QATR can be used for
32 engineering, design, procurement, fabrication, experiments, construction, and testing for the
33 applicant's activities affecting the quality and performance of safety-related SSCs. In addition,
34 the QATR applies a graded approach to the extent commensurate with the SSC's importance to
35 safety. It is incumbent upon the applicant to identify the specific QA requirements that must be
36 met for the scope of activities.
37

38 3.2.1.1.1 Organization

39
40 The QATR is the top-level policy document that delineates the requirements and tasks assigned
41 to the various organizational elements to achieve B&W's stated objectives. Overall policies on
42 quality are established by B&W. Compliance with the QATR and implementing documents is
43 mandatory for all personnel performing activities related to safety.
44

45 The QATR describes the organizational structure, levels of authority, lines of communication,
46 and functional responsibilities for the control of activities affecting quality. The Quality
47 Management function reports to an adequately authoritative level of management. The
48 Program Quality Manager is responsible for assisting with the identification of quality

1 requirements, ensuring such requirements are understood across the program team, assessing
2 the effectiveness of QATR implementation, and reporting results to program and senior
3 management.

4
5 In RAI No. 1, the NRC staff requested that B&W describe the overall scope of activities that
6 apply or could apply to the QATR, in addition to the list of activities already documented (design
7 and procurement of engineering services). In its response, B&W stated that the scope of
8 Revision 3 of the QATR (submitted as Revision 2 of the QATR but hereafter referred to as
9 Revision 3 due to substantial changes to Revision 2) has been modified to include design,
10 fabrication, experiments, construction, and testing of SSCs for the facility.

11
12 In RAI No. 3, the NRC staff requested that B&W describe the function of engineering,
13 procurement, and construction (EPC) as well as its placement in the organizational structure.
14 In its response, B&W stated that the organizational descriptions and chart in Revision 3 of the
15 QATR were revised to more clearly reflect the EPC functions and the responsible organization's
16 role in performing EPC duties.

17
18 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
19 contractors and determined that the organizational controls met the guidance in Section 12.9 of
20 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8

21 22 3.2.1.1.2 Quality Assurance Program

23
24 B&W's QATR documents the requirements for establishing, implementing, and managing the
25 QA program. The QATR identifies the items and activities that are addressed by the program
26 will be documented in applicable policies, procedures, instructions, and controlled documents.
27 The program implements a graded approach to quality. The program provides for the
28 appropriate and necessary indoctrination and training of personnel performing activities that
29 affect quality and ensures that suitable proficiency is achieved and maintained.

30
31 In RAI No. 4, the NRC staff requested that B&W clarify how the definition for safety-related is
32 applicable to the proposed plant design, associated SSCs, and is consistent with
33 ANSI/ANS 15.8. In its response, B&W stated that since the facility is being licensed under
34 10 CFR Part 50, the definition of safety-related SSCs will be restated directly from 10 CFR 50.2
35 and aligned directly with Quality Level (QL)-1. Although 10 CFR Part 70 does not specifically
36 apply to MIPS, nor does it require a QA program, QL-2 was developed to be consistent with the
37 quality requirements of 10 CFR Part 70. In order to specifically address the requirements of
38 10 CFR Part 21 for MIPS, a basic component is defined as aligning directly with QL-1.

39
40 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
41 contractors and determined that the programmatic controls met the guidance in Section 12.9 of
42 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

43 44 3.2.1.1.3 Design Control

45
46 B&W has established an engineering and design control system to document the method of
47 accomplishing, controlling, and preserving engineering and design tasks. B&W stated that
48 procedures will identify the process by which the control of design documents and preparation
49 will be applied and ensure applicable rules, regulations, codes, and standards are implemented.

1 As described below, the NRC staff reviewed the QA measures to be employed by B&W and its
2 contractors and determined that the design controls met the guidance in Section 12.9 of
3 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

4
5 *Design Requirements*

6
7 Design inputs and requirements, including design bases, performance requirements, regulatory
8 requirements, codes, and standards will be identified and documented in the appropriate design
9 requirements documents.

10
11 In RAI No. 5, the NRC staff requested that B&W clarify the phrase in the QATR, "to the extent
12 necessary to demonstrate satisfactory control of input, output, verification and acceptance." In
13 its response, B&W stated that the phrase created ambiguity and removed it from Revision 3 of
14 the QATR.

15
16 *Design Process*

17
18 B&W's design organization is responsible for identifying and controlling the internal and external
19 design interfaces and will coordinate activities among participating organizations. The
20 applicability of standardized or previously proven designs, with respect to meeting pertinent
21 design inputs, will be verified for each application. Deviations from the established design
22 inputs will be documented and controlled.

23
24 The design organization will ensure the final design is relatable to the design input by adequate
25 documentation. Computer design programs used to develop any portion of the facility design or
26 to analyze the design will be controlled. When a design program must be developed, the
27 program will be controlled to ensure that it is fully documented and validated. When changes to
28 previously valid computer programs are made, documented revalidation will be performed for
29 the change and include appropriate benchmark testing.

30
31 *Design Verification*

32
33 Independent design verification will be performed on design documents prior to releasing them
34 for use, including use by another design organization. Accuracy of the design is verified through
35 review of design documents by competent persons other than those who designed the item.
36 The extent of the design verification will be a function of the importance to safety, the complexity
37 of the design, the degree of standardization, the state of the art and the similarity with previously
38 approved designs. Qualification testing will be defined in formal test plans and include
39 appropriate acceptance criteria. Testing will demonstrate the adequacy of performance that
40 simulates the most adverse conditions. Test results will be documented and verified to have
41 met test requirements.

42
43 *Design Documents and Records*

44
45 Design documents and records will provide evidence that the design and design verification
46 processes were performed, will be collected, stored, and maintained for the life of the item.

1 *Commercial-Grade Items*

2
3 B&W will have in place procedural reviews for the use of commercial-grade items to be used in
4 a safety-related application. If a commercial-grade item is modified or selected by special
5 inspection/testing to requirements that are more restrictive than the supplier's published product
6 description, the item will be identified as different in a manner traceable to a documented
7 description of the difference.

8
9 *Change Control*

10
11 Modifications to the facility's SSCs will be procedurally controlled. Design changes will be
12 documented, justified, and subject to control commensurate with those applied to the original
13 design. These measures will include assurance that the design analyses for SSCs or computer
14 codes are still valid. When a significant design change is necessary, the design organization
15 will review and modify the design and reviews the process, as necessary.

16
17 3.2.1.1.4 Procurement Document Control

18
19 B&W's QATR detailed a process to ensure that procurement documents include the
20 requirements necessary for establishing the quality of the procured material, equipment, and
21 services. Design criteria, including applicable specifications, codes, standards, and regulatory
22 requirements will be translated into procurement documents in accordance with approved
23 procedures.

24
25 The QATR stipulates that procurement documents at all procurement levels identify the
26 documentation required to be submitted for information, review, or approval by the purchaser.
27 The procurement documents require access to the supplier's facility and records by designated
28 individuals. Procurement documents will require the supplier to report nonconformances
29 associated with the items or services being procured.

30
31 In RAI No. 6, the NRC staff requested that B&W clarify if the QATR includes requirements that
32 the procurement documents contain sufficient technical and quality requirements to ensure that
33 the items or services satisfy the needs of the purchaser. In its response, B&W stated that in
34 Revision 3 of the QATR the requirement was added that documents contain sufficient technical
35 and quality requirements to ensure that the items or services satisfy the needs of the purchaser.

36
37 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
38 contractors and determined that controls for procurement documents met the guidance in
39 Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

40
41 3.2.1.1.5 Instructions, Procedures, and Drawings

42
43 B&W has established the necessary measures to ensure that quality activities are based on
44 specifications, drawings, procedures, and instructions, as appropriate. These documents will
45 include or reference appropriate quantitative or qualitative acceptance criteria for determining
46 that activities have been satisfactorily accomplished.

1 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
2 contractors and determined that controls for instructions, procedures, and drawings met the
3 guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

4
5 3.2.1.1.6 Document Control

6
7 B&W has established a process to control the review, approval, and distribution of documents,
8 including changes thereto, which prescribe activities affecting quality. The program and
9 implementing procedures establish the requirements to maintain instructions, procedures, and
10 drawings. The distribution of documents will be controlled to ensure that only documents with
11 the prescribed approvals are in use at the locations where the prescribed activity is performed.
12 Major changes to controlled documents will be reviewed and approved by the same
13 organizations that were responsible for the activities and content of the original issue.

14
15 In RAI No. 2, the NRC staff requested that B&W clarify if it was intended to provide a Master
16 Procedures List as stated in the Scope of the QATR. In its response, B&W stated that the
17 Master Procedures List was not intended to be part of the QATR. The list is maintained by the
18 Document/Record Manager. This was clarified in Revision 3 of the QATR.

19
20 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
21 contractors and determined that the controls for documents met the guidance in Section 12.9 of
22 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

23
24 3.2.1.1.7 Control of Purchased Material, Equipment, and Services

25
26 *Supplier Selection*

27
28 B&W has established the necessary measures and procedures to ensure that purchased
29 material, equipment, and services conform to procurement documents. These measures
30 include supplier evaluation and selection including quality evaluations and rating, periodic
31 source surveillances and inspections, audits, and site receiving inspection, as applicable. Prior
32 to supplier selection, the supplier's capabilities to provide items or services in accordance with
33 the requirements of the procurement documents shall be evaluated and unacceptable technical
34 and QA conditions shall be resolved.

35
36 In RAI No. 7, the NRC staff requested that B&W clarify how the QATR provides for audits to
37 show objective evidence of quality furnished by a supplier. In its response, B&W stated that to
38 provide consistency, the term *audit* replaced *assessment* in parts of Revision 3 of the QATR.
39 Additionally, the definition of audit has been added to Appendix C.

40
41 *Work Control*

42
43 B&W's QATR will require the suppliers to establish measures to control performance, as
44 appropriate. Controls may include test plans, review of a supplier's submitted documents,
45 arrangements for source surveillance or inspection, and other technical and administrative
46 interfaces with the supplier in accordance with the procurement documents.

1 *Verification Activities*

2
3 Verification activities shall be accomplished by qualified personnel assigned to check, inspect,
4 audit, or witness the activities of suppliers. B&W's receipt inspection includes verification that all
5 required documentation has been received, reviewed, and accepted and that items conform to
6 the procurement documents.

7
8 *Item or Service Acceptance*

9
10 As noted above, B&W established a process to ensure that purchased items and services
11 conform to procurement specifications. This will also include supplier Certificate of
12 Conformance, source verification, receiving inspection, post-installation test, or a combination of
13 these activities. Receiving inspection will include, as appropriate, review of applicable
14 documentation and attributes of the item, such as cleanliness, shipping damage, or indication of
15 fraud or counterfeit.

16
17 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
18 contractors and determined that the controls for purchased material, equipment, and services
19 met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

20
21 3.2.1.1.8 Identification and Control of Materials, Parts, and Components

22
23 B&W has established the necessary identification and control measures to prevent the
24 uncontrolled use of nonconforming materials, parts, and components, including subdivided
25 items. Materials, parts, and components will be identified by appropriate means. The
26 identification may be on the item or on records directly and readily traceable to the item. The
27 type of identification is established by specifications, drawings, instructions, or procedures.
28 Procedural controls will ensure controls are established for items having a limited shelf and
29 service life.

30
31 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
32 contractors and determined that the controls for identification of material, parts, and components
33 met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

34
35 3.2.1.1.9 Control of Special Processes

36
37 B&W has established the necessary measures to ensure that approved special process
38 procedures are used by qualified personnel in accordance with specified codes, standards and
39 any additional project requirements. The requirements for special process control, including
40 personnel qualification are invoked by specifications, procedures, instructions, or other
41 applicable documents.

42
43 Records will be maintained for the currently qualified personnel, processes, and equipment for
44 each special process, as applicable.

45
46 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
47 contractors and determined that the controls for special processes met the guidance in
48 Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

1 3.2.1.1.10 Inspection

2
3 B&W conducts inspections to ensure that material, equipment, and work conform to quality
4 requirements. The inspection process will be applicable to procurement, construction,
5 modification, and maintenance activities. Inspections will be performed by personnel
6 independent of the work being inspected, but may be from the same organization. Inspection
7 plans will be developed by responsible personnel and approved by the quality organization.
8 Measuring and test equipment (M&TE) used to perform inspections will be identified in
9 inspection documentation for traceability of inspection results. B&W translates technical and
10 QA requirements to inspection procedures, plans, and reports to provide documentation of the
11 work. Only items that have passed the required inspections and tests will be used, installed, or
12 operated.

13
14 B&W will provide for on-the-job training, as appropriate, to ensure inspectors comprehend
15 inspection criteria and methods. Records of inspection personnel qualification will be
16 established and maintained by B&W or the respective contractor.

17
18 In RAI No. 8, the NRC staff requested that B&W clarify how the inspection program applied to
19 fabrication, modification, construction, and maintenance activities, which were originally outside
20 the scope of the QATR. Additionally, the NRC staff asked whether experiment fabrication was
21 within the scope of the QATR. In its response, B&W stated that the inspection program will
22 apply to procurement, fabrication, modification, construction, and maintenance. Further, B&W
23 stated that it does not intend to use the reactor for experiments.

24
25 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
26 contractors and determined that the controls for inspection met the guidance in Section 12.9 of
27 NUGEG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

28
29 3.2.1.1.11 Test Control

30
31 B&W has established the necessary measures and implementing procedures to demonstrate
32 that SSCs will perform satisfactorily in service. The quality organization is responsible to review
33 test procedures, monitor test performance, and evaluate the final results to ensure that test
34 requirements will be satisfied.

35
36 Computer programs to be used for a control function or process will be tested with an approved
37 verification and validation plan and demonstrate required performance over the range of
38 operation of the controlled function or process.

39
40 In RAI No. 9, the NRC staff requested that B&W clarify how the quality organization possesses
41 the technical capability to be the responsible authority to assure that test requirements have
42 been satisfied. In its response, B&W stated that Revision 3 of the QATR was revised to reflect
43 that test results would be documented and evaluated by a responsible authority to assure that
44 test requirements have been satisfied. Implementing procedures will be used to identify and
45 document the responsible authority.

46
47 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
48 contractors and determined that the controls for testing met the guidance in Section 12.9 of
49 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

1 3.2.1.1.12 Control of Measuring and Test Equipment

2
3 B&W's QATR described controls for the calibration, maintenance and use of tools, gages,
4 instruments, and other M&TE used for measurements, inspections, and tests performed to
5 document compliance with specified requirements.

6
7 B&W's control of M&TE includes the following:

- 8
9 1) positive identification of the equipment and its calibration status, including the due date
10 of the next calibration;
11
12 2) use of recognized industry standards;
13
14 3) written procedures describing the calibration control system;
15
16 4) record system to indicate calibration dates, capability of M&TE to perform intended
17 function satisfactorily and identification of personnel performing the calibrations;
18
19 5) recall system to prevent use of equipment beyond its calibration due date; and
20
21 6) a system for corrective action when out-of-calibration or damaged M&TE has been used.
22

23 In RAI No. 10, the NRC staff noted that ANSI/ANS 15.8 allows for calibration and control
24 measures not to be required when normal commercial equipment provides adequate accuracy.
25 In its response, B&W stated that Revision 3 of the QATR was revised to reflect that calibration
26 and control measures will not be required when normal commercial equipment provides
27 adequate accuracy.
28

29 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
30 contractors and determined that the controls for M&TE met the guidance in Section 12.9 of
31 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.
32

33 3.2.1.1.13 Handling, Storage, and Shipping

34
35 B&W's QATR described the necessary measures and implementation of procedures to control
36 the handling, storage, shipping, cleaning, and preservation of materials and equipment to
37 prevent damage, deterioration, or release of radioactive or hazardous material. The above
38 mentioned work is accomplished by qualified individuals in accordance with applicable
39 procedures.
40

41 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
42 contractors and determined that the controls for handling, storage, and shipping met the
43 guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.
44
45
46
47
48
49

1 3.2.1.1.14 Inspection, Test and Operating Status

2
3 B&W's QATR described the measures and implementation of procedures to identify the status
4 of inspections and test operations. The status of inspections and test operations is indicated by
5 tags, markings, records, or other suitable means, provided that the method used ensures that
6 only accepted items are used, installed, or operated.

7
8 Unacceptable items or items of an indeterminate status are identified and controlled to ensure
9 they are not inadvertently installed, used, or operated.

10
11 The quality organization has the responsibility to monitor or conduct inspections or tests and to
12 review data to ensure acceptability.

13
14 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
15 contractors and determined that the controls for inspection, test, and operating status met the
16 guidance in Section 12.9 of NUREG-1537, and ANSI/ANS 15.8.

17
18 3.2.1.1.15 Nonconforming Materials, Parts or Components

19
20 B&W's QATR described the necessary measures and implementation of procedures to control
21 nonconforming items to prevent their inadvertent use or installation until the nonconforming
22 condition is corrected or evaluated to rework, use as is, reject, or repair, as determined by the
23 responsible design organization. These controls include measures for identification,
24 documentation, segregation (as appropriate), and disposition. Physical segregation and
25 marking are B&W's preferred method for identification; however, other means of identification
26 (e.g., tagging, etc.) are acceptable when physical segregation is impractical.

27
28 B&W will document the technical justification for the acceptability of a nonconforming item.
29 B&W's quality organization will periodically review nonconformance data and evaluate for
30 adverse trends. Reports of reviews will be sent to responsible management.

31
32 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
33 contractors and determined that the controls for nonconforming materials, parts, or components
34 met the guidance in Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

35
36 3.2.1.1.16 Corrective Action

37
38 B&W's QATR described the necessary measures and implementation of procedures to
39 determine the cause(s) and take corrective and preventive action to preclude repetition when
40 major and recurring conditions adverse to quality, such as failures, malfunctions, deficiencies,
41 defective material and equipment, and nonconformances are identified. B&W's corrective
42 action program provides for prompt identification, documentation, classification, and correction
43 of the conditions. For conditions adverse to quality and significant conditions adverse to quality,
44 the corrective action process, including the resulting action to resolve the deficiency shall be
45 documented and reported to the appropriate level of management.

46
47 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
48 contractors and determined that the controls for corrective action met the guidance in
49 Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

1 3.2.1.1.17 Quality Assurance Records

2
3 B&W's QATR described the necessary measures and implementation of procedures to ensure
4 sufficient records of completed items and activities affecting quality are collected, maintained,
5 and appropriately stored. B&W's record system is defined, implemented, and enforced in
6 accordance with written procedures, instructions, or other documentation.

7
8 B&W's applicable specifications, procurement documents, procedures, or other documents
9 specify the receipt, storage, preservation, safekeeping, retrieval, types of records to be
10 generated, retention period, and their disposition. B&W has established the necessary
11 measures to ensure that records are legible, identifiable, retrievable, and traceable to the item
12 or activity to which it applies.

13
14 Provisions will be specified for special processed records such as radiographs, photographs,
15 negatives, microfilm, and magnetic media, to prevent damage. Records will be maintained by a
16 supplier and accessible to B&W and its contractors.

17
18 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
19 contractors and determined that the controls for QA records met the guidance in Section 12.9 of
20 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

21
22 3.2.1.1.18 Audits

23
24 The quality organization will have the responsibility to establish the assessment program and
25 requisite implementing procedures. Internal and supplier audits will be scheduled based on
26 periodic reviews. The internal audits will address each QATR section.

27
28 Periodic audits of safety-related activities will be conducted to determine the effectiveness of the
29 quality program.

30
31 Lead auditors will be trained and qualified. Team members will be independent of the area
32 being assessed. The team members will also be adequately trained and qualified.

33
34 Results of the audits will be made available to the relevant B&W or contractor managers, as
35 applicable.

36
37 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
38 contractors and determined that the controls for audits met the guidance in Section 12.9 of
39 NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8.

40
41 3.2.1.1.19 Experimental Equipment

42
43 In RAI No. 11, the NRC staff requested that B&W clarify if the QATR provides controls over the
44 design, fabrication, installation, and modification of experimental equipment to the extent that
45 this impacts safety-related items. In its response, B&W stated that Revision 3 of the QATR was
46 revised to insert Section 19.0, Experimental Equipment. Section 19.0 states that as a
47 commercial facility, MIPS will not have experimental equipment or facilities, nor will they be
48 described in the license and safety analysis report. Changes, tests, and experiments will be
49 managed according to 10 CFR 50.59.

1 As described above, the NRC staff reviewed the QA measures to be employed by B&W and its
2 contractors and determined that the controls for changes, tests, and experiments met the
3 regulatory guidance in 10 CFR 50.59.

4
5 4.0 CONCLUSION
6

7 The NRC staff evaluated B&W's QATR and the supplemental correspondence. The NRC staff
8 concludes that B&W's QA program description adequately addresses the guidance in
9 Section 12.9 of NUREG-1537, Parts 1 and 2, and ANSI/ANS 15.8, and is therefore, acceptable.
10

11
12 5.0 REFERENCES
13

- 14 1. Reynolds, W. E., B&W Technical Services Group, Inc., letter to Document Control Desk,
15 NRC, "B&W Medical Isotope Production System (MIPS) submittal of Quality Assurance
16 Program Description (QAPD) Topical Report Enclosure 1, Abstract Enclosure 2, and
17 Basis for submittal of the Topical Report Enclosure 3," dated June 4, 2010, ADAMS
18 Accession Number ML101600197.
- 19
20 2. Glenn, D. E., B&W Technical Services Group, Inc., letter to Document Control Desk,
21 NRC, "B&W Response to Request for Additional Information Regarding Quality
22 Assurance Program Description Submitted June 4, 2010," dated October 18, 2010,
23 ADAMS Accession Number ML102990311.
- 24
25 3. Voth, Marcus H., NRC, letter to Reynolds, W. E., B&W Technical Services Group, Inc.,
26 "Request for Additional Information Regarding the Babcock & Wilcox Technical Services
27 Group, Inc. Medical Isotope Production System Quality Assurance Program Description
28 Topical Report, MIPS-PP-QA-14, Revision 2," dated September 22, 2010, ADAMS
29 Accession Number ML102640304.

30
31 Principal Contributor: P. Prescott

32
33 Date: May 6, 2011
34