RESPONSE TO FINDING
IR-99-007-01-FIN

Summary of Finding

Section 4.1.3, "Authorization Basis," of DOE/RL-96-0006 requires that the authorization basis be maintained current. Section 3.2 of RL/REG-97-13 specifies that changes to facility design will either be consistent with the existing authorization basis or that the authorization basis will be revised before the proposed changes are implemented. In related parts, the ISMP, Section 3.3.2, "Control of the Authorization Basis," and Section 5.3, "Configuration Management," specify that before any given change is implemented, the impact of the proposed change on the authorization basis will be determined and the necessary changes to the authorization basis will be made.

Section 3.1 of RL/REG-97-13 and Section 3.3.3, "Changes to the Authorization Basis," of the ISMP specify that the process for evaluating and implementing changes will be conducted according to approved procedures under the Contractor's Quality Assurance Program.

Contrary to the above, during the week of October 4-8, 1999, the inspectors found that the Contractor had not established or implemented a process that would ensure that the authorization basis was maintained current with respect to the facility design.

BNFL Inc. response:

1. **Agreement or disagreement with the Finding**

   BNFL Inc. (BNFL) agrees with the Finding.

2. **Reason for the Finding**

   Specific reasons for the Finding include:

   - Procedure K70P551B_0 and Code of Practice K70C551C_0, Preparation, Check, and Approval of Drawing and Sketches, did not identify the need to perform AB screenings or generate ABCNs for design drawings. Although, this requirement is presented in K70P030_3, Design Change Control, the integration of these procedures is inadequate.
   - Procedure K70P528, Managing Change to Control the Authorization Basis, did not provide instructions on coordinating design document approval with closure of the AB maintenance process.
   - Procedure K70P528, provides for deferred resolution of ABCNs, but there is no procedural requirement (in AB or engineering procedures) to complete ABCNs and reconcile the design with the AB before design documents are released for implementation.

   From these the RU concluded that there is no defined point in the project when design and the authorization basis would be reconciled. In all three cases, requirements that would have

provided a more effective and compliant AB maintenance process were not included in the procedure(s). Another cause of the finding was that neither procedure users, supervisors, managers, self-assessment auditors, nor QA surveillance auditors were able to find these program deficiencies before they were identified by the RU.

BNFL conducted a formal root cause analysis on the inadequacy of procedures and their use. The following list of root causes has been formally presented to management and incorporated into a broader corrective action program.

- There was insufficient management attention to procedural compliance and unclear management guidance with regard to AB maintenance requirements, self-assessment processes and results, and training.
- There was insufficient training in the AB maintenance process, particularly with regard to individual and departmental responsibilities for AB maintenance. Additionally, the process was cumbersome and difficult to comprehend, which reduced the effectiveness of the training that was provided.
- There were BNFL schedule and resource constraints that negatively impacted development of a clearly defined and efficient AB maintenance process and consistent implementation of that process. Specifically, more resources should have been applied earlier in Phase B1 to more effectively and consistently integrate the AB maintenance program with the configuration management program for design documents, to develop the required tools, (such as the Design Criteria Database) to enable timely reviews of design documents against AB design criteria, and to provide the requisite training for AB maintenance.
- There were an insufficient number of internal assessments, insufficient attention to detail in assessments, and insufficient review of findings, allowing programmatic problems to go undetected and unresolved.
- The unnecessary complexity of the project procedure system, in combination with the schedule and resource constraints noted above, made it difficult to determine whether all the procedures aligned consistently with AB requirements. Additionally, for AB maintenance, performance and supervisory responsibilities, training requirements, documentation and approval requirements, and closure and tracking requirements were poorly defined.
- There have been conflicting and changing expectations between the RU and BNFL with regard to AB maintenance. Notably, the BNFL interpretation was that design and the AB must be reconciled before “implementation”, which BNFL interpreted as before “procurement or construction”. The RU interpretation, as recently articulated, is that “implementation” is before a design can become the basis for other designs.

3. **The corrective steps that have been taken and the results achieved**

To address the specific reasons for the finding, the following remedial actions have been taken:

- Discussions have been held between BNFL and the RU to align expectations for AB maintenance. Specifically, it has been agreed that by April 24, 2000, the design documents comprising the April Deliverable will be aligned with the AB, in that either revisions of the

AB will have been issued or ABARs issued (when RU approval is required). See Section 5 for the detailed plan.

- To ensure the analytical portions of the AB are aligned with the design, the current HAR and ISAR have been reviewed to develop a definitive list of AB significant and bounding hazards. The list of Design Basis Events (DBE's) developed from ISM Cycle II design reviews will be compared against this list to identify differences and reconcile the design and the AB, as necessary.
- To ensure the technical portions of the AB are aligned with the design, a Design Criteria Database (DCD) has been developed and implemented. The DCD includes all AB design input criteria, including applicable SRD Safety Criteria, implementing standards, and ISAR Fundamental Aspects of Design. BNFL has adopted the Design Input Memorandum (DIM) as a mechanism for AB screening of drawings and specifications. The DIM, in conjunction with the DCD and the Standards Implementation Process Database (SIPD), will provide the necessary screening of design documents against AB design input criteria. Approved DIMs will attest to the fact that the design is aligned with the AB design input criteria.

4. The corrective steps that will be taken to avoid further Findings

For corrective steps needed to address the specific reasons for the finding, BNFL has reviewed the authorization basis maintenance program and is refining the process. Detailed reviews have been initiated to align AB maintenance procedures with the design program procedures. A revised AB maintenance program will be implemented by April 24, 2000, in order to ensure that the AB is maintained current with respect to the facility design. The revised AB maintenance program will require that (other than for proceed at risk exceptions) the AB will be updated before a design change or design evolution is implemented such that the revised design document can become the basis for other designs. Key features of the proposed new AB maintenance program are as follows:

- As discussed in Section 3, the DIM will be used in conjunction with the DCD and SIPD to provide for the necessary "screening" of design documents against AB design input criteria. Any proposed changes causing inconsistency with the AB will require engineering-generated ABCNs. Revised DIMs will be required whenever the parent document is revised (i.e., to ensure continued consistency with the AB).
- ES&H will review design documents to ensure that design changes do not impact the analytical safety basis. Also, improvements will be made to the AB change process to ensure ABCNs, Safety Evaluations, and ABARs are linked to one another and to the design documents that generated the AB change. This will be done by related documents by number and closeout sequencing. ES&H will track and review the listing of ABCNs and Safety Evaluations to ensure all applicable AB change activities are completed. Database tools will be used to more effectively track these various documents. Procedural requirements will be developed and implemented to ensure that AB screening and change documents are properly dispositioned before associated design documentation is implemented.

- BNFL will develop an "ES&H Safety Checklist". This checklist will be used by the ES&H department to review documents. The checklist will ensure nuclear, process, industrial, and environmental safety are considered and the AB analysis is maintained before ES&H approval of new designs or design changes.
- Procedural changes will be made to ensure close linkage between the design, design change process, and the AB change process. Design changes will not be approved for implementation until AB reconciliation has been completed. Specific procedural weaknesses and inconsistencies noted by the RU in Finding IR-99-007-01-FIN (to K70P528, K70C528, K70P551, and K70C551) have or will be corrected.

For corrective steps needed to address the root causes for the finding, BNFL management has reviewed the recommendations of root cause teams and has directed the following actions to correct or mitigate root cause deficiencies.

- Insufficient Management Attention - Meetings have been held with individuals performing the remedial and corrective actions discussed above to clarify BNFL management expectations regarding authorization basis maintenance. Additional corrective actions associated with insufficient management attention will be identified and implemented in conjunction with the QA program recovery plan discussed in the cover letter.
- Insufficient Training - BNFL will develop and deliver new AB maintenance training modules to all applicable project employees. This training will be based on the revised AB maintenance process described in this section. As appropriate, AB findings lessons learned will be incorporated into training plans.
- BNFL Schedule and Resource Constraints – The necessary resources to align the AB and facility design by April 24, 2000 have been identified and put into place. Additionally, resources required to revise the AB maintenance program have been identified and put into place. The additional resources required to implement the revised AB maintenance program, including performing the necessary training and surveillances, are currently being reviewed and will be put into place prior to April 24, 2000.
- Insufficient Internal Assessments - A QA surveillance of the revised AB maintenance program will be performed by June 30, 2000. Additional corrective actions associated with insufficient internal assessments will be identified and implemented in conjunction with the QA program recovery plan discussed in the cover letter.
- Complexity of Documents - Where there are multiple requirement documents and multiple procedure levels and implementing departments involved in the AB maintenance program, BNFL will combine and delete procedures as necessary to ensure more efficient usage. Procedures will be written and reviewed to ensure greater coupling and consistency both vertically (from top-level requirements down through the lowest level design guides) and horizontally (across all departments having responsibility for program implementation).

- Conflicting Interpretations – To help ensure alignment of expectations for AB maintenance, BNFL will issue to the RU a detailed AB Maintenance Proposal, along with an ABAR, by February 29, 2000. When agreement is reached, expectations regarding AB maintenance will be clearly defined and the path forward established.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Full compliance with program requirements will be achieved when the design and the AB are in alignment, the revised AB maintenance program has been implemented, and necessary training completed. This will occur on or before April 24, 2000. Alignment of the design and the AB is not dependent on the RU's approval of the proposed "proceed at risk" option. The QA surveillance of the revised AB maintenance program will be completed by June 30, 2000.

The following outline shows the detailed plan for these activities.

By March 1, 2000:
- Formal program description of revised AB maintenance program issued to RU
- ABAR issued for "proceed at risk"
- Meeting with RU on AB maintenance program

By April 1, 2000:
- Design documents reviewed for AB consistency using either a DIM or AB screening
- DBE's identified from ISM Cycle II and compared against list of AB significant and bounding hazards
- ABAR for "proceed at risk" approved
- Procedure changes identified for revised AB maintenance program

By April 24, 2000:
- Necessary ABCNs and SEs approved
- AB revisions issued for all changes not requiring RU approval
- ABARs issued for all AB changes requiring RU approval
- Engineering and AB procedures issued to reflect new AB maintenance program
- Training completed for all affected project personnel
- Deficiency Reports issued for open ABARs in accordance with "proceed at risk" to ensure appropriate tracking and closure

By June 30, 2000:
- QA surveillance of revised AB program complete and effectiveness of the revised AB maintenance program determined

Full closure of root cause corrective actions is scheduled to coincide with the completion of the QA Program Recovery Plan on August 1, 2000.

RESPONSE TO FINDING
IR-99-007-03-FIN

Summary of Finding

Section 5.3.2, "Instructions and Procedures," of the Quality Assurance Program and Implementation Plan (QAPIP) requires processes that affect quality be conducted using approved instructions and procedures.

a. Procedure K70C528A_1, "Code of Practice for Managing Changes to Control the Authorization Basis," dated November 1999, Appendix 5, "Managing Changes to the Radiation Protection Program," requires the manager of the River Protection Project-Waste Treatment Plant (RPP-WPT) proposing a change to the Radiation Protection Program (RPP) to prepare an authorization basis change notice (ABCN).

Contrary to the above, revision 3 of the RPP was issued on November 15, 1999, without generating an ABCN. (IR-99-007-03a-FIN)

b. Procedure K70C528A_1, Section 5.0, "Authorization Basis Change Notice (ABCN)," requires the generation of an ABCN if a proposed change affects the authorization basis.

Contrary to the above, during preparation of revision 5 of the QAPIP, screening assessment SCA-W375-99-00123, revision 0, dated August 5, 1999, for determining the affect the revision would have on the authorization basis, identified that the change would affect the Standards Requirements Document (SRD) and the ISMP; however, as of November 23, 1999, no ABCN had been generated to document the changes to the SRD and ISMP. (IR-99-007-03b-FIN)

These examples of failure to follow procedures were considered an inspection Finding.

BNFL Inc. response:

1) Agreement or disagreement with the Finding

BNFL agrees with Findings 03a and 03b.

2) Reason for the Finding

The specific reason for Finding 03a is:

- Procedure K70P528, Managing Change to Control the Authorization Basis, requires that an ABCN be written for changes to the Radiation Protection Program. Revision 3 to the RPP was executed without an ABCN. The BNFL personnel involved with the change had believed that since the change documentation was generated for Revision 2 to the RPP, and that Revision 3 contained only minor additional changes upon which the RU based its approval, that no additional change documentation was required. However, procedure

K70P528 did not provide the option of not issuing an ABCN for special cases. The procedural requirement for an ABCN did not address in sufficient detail how changes to AB documents such as the RPP should be treated when those changes are a result of incorporating RU comments on previous revisions. BNFL personnel failed to recognize the procedural requirement as applicable in this case.

The specific reason for Finding 03b is:

- Procedure K70P528 requires that an ABCN be written if a proposed change affects the authorization basis. The originator of the proposed change to the QAPIP (Revision 4A) identified that the QAPIP change would affect the Safety Requirements Document (SRD) and the Integrated Safety Management Plan (ISMP). However, Revision 4A to the QAPIP was issued without an ABCN for the changes to the SRD and ISMP. The originator of the QAPIP change failed to follow procedural instructions due to confusion over whom was responsible for generating the ABCN. The owner of the QAPIP believed the ES&H Department was responsible for preparing all ABCNs for changes to AB documents under its control (the SRD and ISMP) regardless of the origin of the change. The QAPIP owner was mistaken, as K70P528 and K70C528 clearly instruct the originator of a change to prepare ABCNs, etc.

Another contributing reason for both findings is that the internal surveillance mechanisms failed to detect these deficiencies.

3) The corrective steps that have been taken and the results achieved

To address the specific reasons for the findings, the following remedial actions have been taken:

- The two individuals responsible for the failings that resulted in these two findings have been coached on the specific errors committed and instructed on the need for strict compliance with procedural requirements.
- An ABCN has been issued for Revision 3 of the RPP.
- ABCN's have been issued for changes to the ISMP and SRD created by the revision of the QAPIP.

4) The corrective steps that will be taken to avoid further Findings

To address the specific reasons for the finding, BNFL has begun the process of revising the authorization basis maintenance program. As part of that process, BNFL will revise the K70C528 code of practice to remove ambiguities and inconsistencies within the code of practice, and between the CoP and other project procedures. A clear path will be established for preparation, review, and approval of all AB documents. Guidance will be included that specifically requires a screening evaluation (and, as necessary an ABCN and SE) for applicable changes to any AB document. The current CoP tends to address how the AB is screened if other documents conflict with the AB. It does not address how the AB, itself, is screened and

modified if another AB document is changed. Other governing project change control procedures will be reviewed and revised to ensure consistency among all procedures.

Finding IR-99-007-03-FIN has root causes related to procedural problems that are similar to those root causes discussed in Finding IR-99-007-01-FIN. The corrective actions to prevent recurrence outlined in Section 4 of Finding IR-99-007-01-FIN are also applicable to this finding.

5) The date when full compliance with the applicable commitments in the authorization basis will be achieved

Full compliance with program requirements will be achieved when the revised AB maintenance program is in place and all training on the new program has been completed, by April 24, 2000. The QA surveillance of the revised AB maintenance program will be completed by June 30, 2000. Full closure of root cause corrective actions is scheduled to coincide with the completion of the QA Program Recovery Plan on August 1, 2000.

RESPONSE TO FINDING
IR-99-007-05-FIN

Summary of Finding

Section 4.2.2, "Records," of the QAPIP requires that records that contain errors or discrepancies are to be corrected, reviewed, and approved by the originating organization.

Contrary to the above, ABCN-W375-99-0044, revision 0, issue on June 4, 1999, was generated to document revision 2 of the RPP, and was changed by the originator on June 8, 1999, after it was issued in Project Document Control, without first obtaining review and approval by the origination organization.

BNFL Inc. response:

1) Agreement or disagreement with the Finding

BNFL agrees with this Finding.

2) Reason for the Finding

The specific reason for the Finding is:

- The originator of ABCN-W375-99-0044 did not consult project procedures before he made a "pen and ink" change to a project record. He did not use the approved process for making changes and was, thus, in violation of QAPIP requirements.

3) The corrective steps that have been taken and results achieved

To address the above issue, the following remedial actions have been taken:

- The originator of ABCN-W375-99-0044 has been counseled and instructed to re-read the code of practice on revising procedures, K13C003, Code of Practice for the Production of Process-Based Procedures.
- The change to ABCN-W375-99-0044 has been corrected. Since the change to ABCN-W375-99-0044 was technically correct and procedurally wrong, a revision to the ABCN form has been made in accordance with project procedures.

4) The corrective steps that will be taken to avoid further Findings

A change to appropriate project procedures will be made to delineate the correct process for correcting factual errors in procedures, forms, etc.

BNFL will perform an internal assessment to determine the extent of the inappropriate practice of lining out document records. Depending on the results of this audit, BNFL will determine what additional corrective actions are required.

Additional corrective actions associated with procedural noncompliance will be identified and implemented in conjunction with the QA program recovery plan discussed in the cover letter.

5) The date when full compliance with the applicable commitments in the authorization basis will be achieved

The internal assessment on the extent of the inappropriate document change problem will be completed by March 17, 2000. Full closure of root cause corrective actions is scheduled to coincide with the completion of the QA Recovery Plan on August 1, 2000.

RESPONSE TO FINDING
IR-99-007-06-FIN

Summary of Finding

Section 3.1 of RL/REG-97-13 states that the processes associated with evaluation and implementing changes are, themselves, important to safety and that implementation of changes shall be accomplished by qualified personnel. Implementation of this requirement is described in Section 3.3.3 of the ISMP, which states that "the change management program includes the use of qualified personnel."

Contrary to the above, during the week of October 4-8, 1999, the inspectors found that of the 15 screening assessments they reviewed, 6 were performed or reviewed by individuals who had not completed the authorization basis training module. Of the 7 safety evaluations reviewed by the inspectors, 6 were performed or reviewed by individuals who had not completed the authorization basis training module.

BNFL Inc. response:

1) Agreement or disagreement with the Finding

BNFL agrees with this Finding.

2) Reason for the Finding

Specific reasons for the finding include:

- A number of project personnel failed to recognize that they required formal training to perform AB screening assessments and safety evaluations.
- Supervisors and managers failed to recognize that untrained individuals were performing AB maintenance activities. Also, they failed to adequately identify to employees the types of training required (classroom, required readings) before performing AB maintenance.
- Project self-assessments and QA surveillances failed to detect the problem.

3) The corrective steps that have been taken and the results achieved

As discussed in the response to Finding IR-99-007-01-FIN, actions are underway to align the design documents comprising the April Deliverable with the AB by April 24, 2000. As part of this effort, new screening assessments are being completed independent of the screening assessments reviewed during the RU inspection. In cases where screening assessments or safety evaluations were performed by untrained individuals, those will be superceded by new screening assessments or safety evaluations being produced as part of the alignment of the design with the AB by April 24, 2000.

4) The corrective steps that will be taken to avoid further Findings

BNFL will perform an internal assessment to determine the extent of the practice of untrained persons performing quality-related work. Depending on the results of this audit, BNFL will determine what additional corrective actions are required.

Finding IR-99-007-06-FIN has root causes related to training and procedural problems that are similar to those root causes discussed in Finding IR-99-007-01-FIN. The corrective actions to prevent recurrence outlined in Section 4 of Finding IR-99-007-01-FIN are also applicable to this finding. In particular, these corrective action items will address the need for management and the training program to make employees aware of training and qualification requirements and the need to enforce these requirements.

5) The date when full compliance with the applicable commitments in the authorization base will be achieved

The internal assessment on the extent of using untrained personnel will be completed by March 10, 2000. Revisions to the training implementing procedures will be completed by March 24, 2000. Completion of the new AB screening assessments and new safety evaluations, which will supercede previous ones performed by untrained individuals, will be completed by April 24, 2000. Full closure of root cause corrective actions is scheduled to coincide with the completion of the QA Program Recovery Plan on August 1, 2000.

RESPONSE TO FOLLOW-UP ITEMS

IR-99-007-02-IFI

The inspectors concluded that the Contractor's authorization basis amendment process was disjointed, confusing, and appeared at times to be inconsistent with regulations. The procedural issues are considered a program weakness.

Response:

BNFL agrees with this weakness and follow-up item. Project procedures and codes of practice (CoP) have created confusion and inconsistency within the AB change control program. BNFL is in the process of revising the AB maintenance program. One important element of that revised program will be the reconciliation of all procedures and CoPs to ensure consistency and accuracy. Some documents will be deleted and their requirements combined into fewer remaining documents, thus improving consistency and efficient usage. The CFRs and top-level requirement documents will be reviewed to ensure project procedures correctly incorporate all requirements.

Due Date: April 24, 2000.

IR-99-007-04-IFI

The Contractor had not appropriately implemented the requirements of RL/REG-97-13 and Section 3.3.3 of the ISMP as they relate to notification of the RU of changes to authorization basis documents implemented without prior RU approval. This was considered a program weakness.

Response:

BNFL agrees with this weakness and follow-up item. Beginning immediately, BNFL will notify the RU, in the form of docketed correspondence, of all changes to the authorization basis. This will be proceduralized by revision to K70C528, Code of Practice for Managing Changes to Control the Authorization Basis.

Due Date: April 24, 2000.