

Clarification & Guidance
DOE-0342 Chronic Beryllium Disease Prevention Procedure

Proposed Reviewed Rejected Accepted Approved for Use Procedure Updated Complete N/A

ID Number: **Title/Subject:** Configuration Control of DOE-0342 and Implementing Procedure

Initiated by: Darrell J. Riffe **Company:** MSA **Date:** 08/17/2011 **Ph #:** (509) 376-0596

Issue/Concern/Affected Step(s):

Not applicable, as process is not defined in existing version of DOE-0342.

Discussion:

No procedurally defined process exists that documents the configuration control process for DOE-0342 or its forthcoming implementing procedures, other than that specified by the CBDPP Resolution Form process.

DOE-0342 has historically been a stand-alone document, with various supporting attachments and appendices. The first revision to DOE-0342 will incorporate the use of implementing procedures directly referenced within DOE-0342, which is a deviation from the current version. These procedures will be more comprehensive and prescriptive than the language previously contained within DOE-0342 and will better define certain beryllium program processes and elements. As these implementing procedures are developed, they will be published and referenced as appropriate within DOE-0342.

It is expected that various revisions to DOE-0342 will be required, as well as revisions to those procedures invoked by DOE. As such, a rigorous configuration control process is required to ensure that: (1) only the most current revisions are available for use, and (2) historical knowledge of revisions is retained for reference.

The review process for resolution forms has two components. The determination of whether a change is "Minor" or "Major" affects the review and approval process by the CBDPP Committee. The determination of whether a change is "Significant" or "Not Significant" is made by RL/ORP. Significant changes require formal RL/ORP approval. Not Significant changes merely require RL/ORP concurrence.

Recommended Resolution:

Develop a process that defines document configuration control of DOE-0342 and any procedures invoked through direct reference within DOE-0342, and insert such language within DOE-0342. This process will invoke processes defined by MSC-MP-41080, the Hanford Site Wide Management Plan.

Existing Language in CBDPP:

Not applicable, as no language for document configuration control exists within the current version of DOE-0342. The proposed language below will be new.

Proposed Language:

This will be added as an Appendix in DOE-0342.

The CBDPP Committee recognizes that revisions to DOE-0342, the *Hanford Chronic Beryllium Disease Prevision Program (CBDPP) Plan*, and its implementing procedures will be required to adjust, clarify, or augment programs and processes to ensure usability, clarity, and compliance. Revisions or changes to DOE-0342, or any procedure that implements DOE-0342 requirements through direct reference in DOE-0342, must adhere to a defined and rigorous change control process. The Hanford CBDPP Committee will enforce the process defined within this section to ensure that such revisions receive appropriate review, approval and configuration control.

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DEFINITIONS:

The following definitions are applicable to this configuration control process:

- A **Minor Change** shall be any change to DOE-0342 or any of its supporting procedures and their attachments or appendices that meets the following conditions:
 - Reformatting that does not alter the technical content; correcting grammar, typographical, or spelling; renumbering sections, pages, tables, figures, or attachments that do not affect the chronological sequence of work; changing the title or number of the document;
 - Updating organizational names or titles, provided organizational responsibilities are not changed;
 - Updating or changing reference citations where the technical requirements are equivalent or more rigorous; or
 - Clarifying language that does not introduce conflicting language, add, or change requirements.
- A **Major Change** shall be any change to DOE-0342 or any of its supporting procedures that does not conform to the definition of Minor Change, above.
- **Note:** The CBDPP Committee recognizes that revisions may be presented that are not explicitly described in the definition of Minor Change, above. In such cases, the CBDPP Committee reserves the right to designate such changes as Minor Changes through CBDPP Committee vote approval and concurrence by DOE-RL and DOE-ORP.
- A **Not Significant Change** shall be any change that doesn't significantly impact how the CBDPP is implemented in the field. All Minor changes are considered to be Not Significant changes. While most Major changes will also be Significant changes, certain Major changes may be deemed as Not Significant. Changes determined to be Not Significant only require concurrence by DOE-RL and DOE-ORP representatives.
- A **Significant Change** shall be any change that impacts how the CBDPP is implemented in the field. Significant changes will normally require additional training of workers to implement. Significant changes require formal approval from the Managers of the RL and ORP field offices. DOE-RL and DOE-ORP have the sole authority to determine whether a Major change is also a Significant change.

Minor changes to documents, such as editorial corrections, do not require the extent of review and approval required for Major changes. Minor changes shall be specified, and documented within the revision process, as defined in the following paragraphs. The Hanford CBDPP Committee Chair and Co-Chair will approve Minor changes to DOE-0342 and any of its explicitly designated implementing procedures, with concurrence by DOE-RL and DOE-ORP representatives.

Major changes to documents affecting the technical bases established in DOE-0342 or procedures that explicitly support the implementation of DOE-0342 shall be reviewed and approved by the Hanford CBDPP Committee and the same organizations that performed the original review and approval, unless other organizations are specifically designated (i.e., those specifically affected by the change). The Hanford CBDPP Committee and any other reviewing organization(s) shall have access to pertinent data or information upon which to base their approval. Specifically designating other organizations is permitted in cases where organizational responsibilities and authorities have changed or review/approval

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requests are no longer valid. Once the CBDPP Committee and other reviewing organizations have approved the document, the document shall go to RL/ORP for review and determination of significance.

DOE-0342 CHANGE CONTROL PROCESS:

1. The Hanford CBDPP Committee shall be designated as the *Technical Authority* for DOE-0342 and all of its directly referenced implementing procedures. Site-Wide Standards shall be designated as the *Owner* of procedures that support the implementation of DOE-0342. DOE-0342 and implementing procedures explicitly invoked by DOE-0342 that define processes, specify requirements, or establish design shall be identified, prepared, reviewed, approved, issued, revised and used in accordance with this process.
2. The Hanford CBDPP Committee shall review any revisions of DOE-0342 and of its supporting procedures, including their associated attachments and appendices for adequacy, completeness, and correctness before approval and release by the CBDPP Committee. After approval by the CBDPP Committee, the revised document shall be distributed for required approval signature and released through the Site-Wide Standards organization.
3. Major changes are any changes that do not meet the criteria of Minor changes, excepting the notation within the definitions of this section. Major changes to DOE-0342 and its associated implementing procedures shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization shall have access to pertinent data or information upon which to base its approval. Specifically designating other organizations is permitted in cases where organizational responsibilities and authorities have changed, or review/approval requests are no longer valid.
4. Minor changes to DOE-0342 and its associated implementing procedures, such as editorial corrections; do not require the extent of review and approval required for Major changes. Minor changes shall be specified, and their bases documented through the use of a Resolution Form or Document Change Revision Notice. Resolution Forms and/or Documented Change Revision Notices shall be maintained within the change control systems defined below.
5. Revisions to DOE-0342 shall be accomplished with associated revision numbers. Not Significant changes to DOE-0342 will require a Minor Revision number modification (e.g., Not Significant revisions to Revision 1 would be denoted as Revision 1a, 1b, etc.). Significant changes to DOE-0342 will require a Major Revision number modification (e.g., a Significant revision to Revision 1 would be denoted as Revision 2).
6. Site-Wide Standards shall maintain all revisions of DOE-0342 and any explicitly identified implementing procedures for configuration control purposes, along with change summaries that define the reasons and bases of the change(s). The process for distribution of DOE-0342 and its associated implementing procedures shall ensure the latest approved revisions are available to the personnel using these documents, and that appropriate notices and documents are posted with notice on the Hanford Site-Wide Standards and Hanford Onsite Contractors' procedure pages. Past revisions shall be removed from the same locations. All retired revisions and their associated change notices (including the notice that retired the document) will be maintained in electronic format by both the Site-Wide Standards organization and by the recording secretary of the CBDPP Committee. Electronic copies of superseded or canceled controlled documents shall be identified and maintained as records for their specified retention period.

