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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

SUPPLEMENT No. 5

Document Requirements for Experiments and Research

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**U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Office of Geologic Repositories**

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SUPPLEMENTAL QUALITY ASSURANCE REQUIREMENTS

Document Requirements for Experiments and Research

1.0 GENERAL

The Supplement provides minimum requirements for experiment and research documents. It supplements the OGR QA Plan. The requirements in this Supplement are to be used in conjunction with the requirements embodied or referenced in the governing QA plans and procedures.

2.0 PURPOSE

The purpose of this Supplement is to specify document requirements for experiments and research for geologic repository projects.

3.0 SCOPE

The requirements of this Supplement are applicable to all experiments and research for geologic repository projects.

The requirements of this Supplement are not, by themselves, sufficient to assure that data so obtained will be suitable for licensing. OGR participating organizations will apply, as a minimum, the following requirements for documentation of experiments and research. Data obtained from experiments and research for formulating decisions affecting public radiological health safety, waste isolation, or used to support a license application shall be conducted under the documentation controls outlined in this document and other applicable requirements identified in the OGR QA Plan.

4.0 DEFINITIONS

None

5.0 REQUIREMENTS

OGR participating organizations will apply, as a minimum, the following requirements when conducting experiments and research. The requirements set fourth in this section shall be used as the bases for experiments and research control.

5.1 Documentation

Documentation of experiments and research shall be prepared using bound logbooks or other suitable means to provide a written record of the experiment or research.

5.2 Initial Entries

Prior to initiation of the experiment or research, the following entries as a minimum, will be made.

- (a) Title of the experiment or research.
- (b) Name of the individual(s) performing the experiment or research and any additional witnesses to the experiment or research.
- (c) Qualifications of the individual(s) performing or witnessing the experiment or research or references to such qualification records.
- (d) Description of experiment's objective.
- (e) Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- (f) Record retention time, if longer than three (3) years from the date of the last entry.
- (g) A description of the procedures that will be followed, or sequence of steps in the conduct of the experiment or research.

5.3 In-process Entries

Entries to be made during the experiment, daily or as appropriate, shall be sufficiently detailed that another competent experimenter could repeat the experiment and shall include:

- (a) Date and name of individual making the entry.
- (b) Description of the experiment or research attempted, including detailed step-by-step process followed.
- (c) Description of any conditions which may adversely affect the results of the experiment or research.
- (d) Identification of samples used and any additional equipment and materials not described in Section 5.2.
- (e) All data taken and a brief description of the results to include notation of any unaccepted results.
- (f) Any deviations from the planned experiment or research.
- (g) Any interim conclusions reached, as appropriate.

- (h) Final results and a summary of the outcome of the experiment or research. Also a discussion of whether the experiment's objectives (see 5.2d above) were achieved.

5.4 Final Entries

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.