

## **APPENDIX C: QUALITY ASSURANCE PLAN FOR THE HTR-PROTEUS EXPERIMENTS**

### **C.1. INTRODUCTION**

The International Atomic Energy Agency has established a Co-ordinated Research Programme (CRP) on the Validation of Safety-Related Physics Calculations for Low-Enriched Uranium Fueled HTGR'S. This involves participation of all countries with major HTGR technology development programs including Germany, Japan, Peoples Republic of China, Switzerland, the United States, and the Russian Federation.

The objective of the Co-ordinated Research Programme is to provide safety-related physics data for low-enriched uranium (LEU) fueled gas-cooled reactors for use in validating reactor physics codes used by the participating countries for analysis of their designs.

The main activities within the Co-ordinated Research Programme are being carried out by the international project at the PROTEUS critical facility, Paul Scherer Institute (PSI), Villigen, Switzerland. Critical experiments will be conducted for HTGR-LEU systems to determine core reactivity, flux and power profiles, reaction rate ratios, the worth of burnable poisons, and the effects of moisture ingress on core reactivity and control rod worth. These experiments will be conducted over a range of experimental parameters such as carbon-to-uranium ratio, fuel packing fraction and simulated moisture concentration.

The PROTEUS facility has been in existence since the late 60s and critical experiments have been conducted for gas-cooled, fast reactors and light water high converter reactor systems. For the HTGR-LEU experiments the PROTEUS facility has been modified to accommodate the new experiments. The modifications consist of several new graphite blocks, upper reflector, safety and shutdown rods, and control rods. LEU pebble fuel from the AVR has been provided by Germany for the HTR-PROTEUS experiments.

The US participation in the HTR-PROTEUS experiments is being co-ordinated by the Oak Ridge National Laboratory (ORNL) who is a program participant in the United States Department of Energy (DOE) Commercial Modular HTGR Program. As a MHTGR program participant ORNL is required to have a Quality Assurance program that meets ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facilities" as endorsed by USNRC Regulatory Guide 1.28, Revision 3 on activities that affect the quality of "safety-related" items. The QA requirements imposed on ORNL must be applied to any activity being performed for ORNL by another organisation.

The United States is participating in the planning, conducting, and analysis of the experiments, the objective being to obtain data for validation of reactor physics codes used within the USDOE Commercial MHTGR program. Therefore, the scope of the QA Program is focused on conducting the experiments and the gathering, recording, and analysis of the measured data. This Plan defines the applicable Quality Assurance requirements for the US participation in the HTR-PROTEUS experiment.

## C.2. ORGANISATION

This section of the QA Plan describes the organisations responsible for the establishment and execution of the HTR-PROTEUS QA Program.

PSI has the responsibility for operation of the PROTEUS facility and overall management of the various experiments that are to be conducted. Within PSI a Project Manager has been appointed with overall responsibility for the HTR-PROTEUS project. The Project Team consists of the Project Manager, two Task Leaders and other support personnel. In addition countries participating in the IAEA CRP will provide on-site support personnel throughout the experiments.

The responsibility for PSI management of the HTR-PROTEUS experiments is implemented through an organisation consisting of the Laboratory Head for Reactor Physics and Systems Engineering, the Project Manager and the two Task Leaders. The responsibilities for the Laboratory Head and Project Manager are as follows:

- The Laboratory Head for Reactor Physics and Systems Engineering has overall accountability for activities and results of the laboratory. This accountability and authority are assigned to him by the PSI Director through the Department Head for Nuclear Energy Research. The Laboratory Head is accountable for administration, planning, leading, organising, and controlling all activities of the Laboratory within the guidelines established by the Institute's Director. This includes forecasting and long-range planning; the establishment of objectives; the approval of program plans, schedules, and budgets; the establishment of procedures and organisational structure; the organisation of an effective internal and external information transfer system; and the measurement of performance against laboratory objectives.
- A Project Manager is responsible for the overall management of an assigned research program. This includes meeting established budgets, schedules, and ensuring that the technical and quality assurance objectives of the program are met.

The specific QA responsibilities for individuals involved in the PROTEUS experiments are as follows:

### **Laboratory Head for Reactor Physics & Systems Engineering**

Approve the HTR-PROTEUS QA Plan and the QA procedures that implement the QA Plan (procedures are the appendices to the QA Plan).

### **Project Manager**

- Control all QA procedures that implement the QA Plan.
- Review all modifications to the PROTEUS facility that can affect the experiments to assure that design criteria are met.
- Approve purchase orders for test-related equipment above a certain expenditure level.
- Identify and ensure maintenance of QA records. Determine the method and duration of storage.

### **Experiments Task Leader**

- Assure that Experiment and Measurement Plans are prepared and approved according to requirements in QA Plan.
- Assure that experiments are conducted according to appropriate documents (i.e., Experiment Plans and Measurement Plans).
- Identify test equipment that requires calibration.
- Determine equipment or items that require a preparation of a Procurement Document.
- Control and approve software used for gathering and/or analysis of measurement data.

### **Analysis Task Leader**

- Control and approve software used for analytical tasks.
- Categorise computer software to determine appropriate QA (verification, validation, configuration control).

### **ORNL**

- Prepare QA Plan and Procedures
- Audit HTR-PROTEUS Project and document results of audits.
- Since there is no Quality Assurance organisation within PSI, the preparation of a QA Plan, QA procedures, QA audits and surveillances will be provided by ORNL QA personnel throughout the life of the program.

### **C.3. QUALITY ASSURANCE PROGRAM**

The HTR-PROTEUS Project has established and implemented a QA Program in accordance with the applicable portions of ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facilities" as described in this QA Plan. Implementation of the QA Program is accomplished through the use of HTR-PROTEUS QA procedures. These procedures are written to identify the activities to be performed, the individuals responsible and to provide the control of activities to the extent consistent with their importance.

The operation of the reactor facility is the responsibility of PSI and its operators shall be qualified and certified in its operation. This is accomplished through a formal Reactor Operators training program that is conducted by the Reactor School Section followed by an examination conducted by the Swiss Nuclear Safety Authority. Experimentalists from several countries shall be involved in the planning and conducting of experiments and they shall receive appropriate instructions in the safe utilisation of the facility. According to the rules provided in the "Betriebsvorschriften" (Operating rules) for the PROTEUS facility (which are officially approved by the PSI Safety Director and subsequently by the PSI Director and checked by the Swiss Hauptabteilung für die Sicherheit der Kernreaktoren) this is the responsibility of the PROTEUS licensed reactor physicists.

### **C.4. DESIGN CONTROL**

Design control applies to the degree that the PROTEUS test facility will be modified to accomplish the HTGR LEU fuel experiments. Facility modifications shall be defined and documented in drawings and the PROTEUS Safety Report. These documents shall be

reviewed prior to issuance by the Project Manager and the appropriate Task Leader to ensure that the appropriate design criteria were met. These requirements will apply to future facility modifications that are required to perform the HTR experiments.

### **C.5. PROCUREMENT DOCUMENT CONTROL**

This section applies to the procurement of hardware items needed for the facility modifications and procurement of test related equipment.

The Task Leader is responsible for the preparation of purchase requisitions that are forwarded to the PSI Central Purchasing Department for preparation and placement of purchase orders. Procurement activities for hardware, components, materials, or services from suppliers are initiated by the HTR-PROTEUS user by preparation of a purchase requisition. The requisition shall include, either directly or by reference, the following:

- descriptive title of the item or service desired;
- complete list of applicable drawings, including the revision level;
- complete list of technical specifications, including applicable changes; and
- QA requirements

When all approvals have been obtained the requisition is forwarded to the Purchasing organisation for placement of the purchase order. This approval cycle provides the necessary review of the procurement package to ensure that appropriate, technical and quality assurance requirements are adequately and clearly stated. After order placement, purchase order revisions to any of the technical requirements are reviewed, approved, and processed in the same manner as the original requisition.

### **C.6. INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

The HTR-PROTEUS shall use QA Procedures to ensure that all activities affecting quality are planned, controlled, and documented as appropriate. Approval and changes to those procedures are controlled by the Project Manager. QA procedures are mandatory for all personnel performing and/or verifying quality-related activities for the HTR-PROTEUS. (Ref Sect. 11).

Based on the activity being performed, written instructions are provided through the use of experiment plans, measurement procedures, and operating instructions. As a minimum, all these written instructions are reviewed and approved by the Project Manager and appropriate Task Leader.

### **C.7. DOCUMENT CONTROL**

Control of procedures that implement the QA Program is maintained by the HTR-PROTEUS Project Manager. As a minimum, these procedures are reviewed by the Project Manager, and both Task Leaders. The procedures and subsequent revisions are approved by the Laboratory Head for Reactor Physics and Systems Engineering.

Only one official version of the approved procedures and plans will exist. The official versions will be kept in the control room of the PROTEUS facility. Copies of these documents

may be made and distributed for informal use. These unofficial copies shall be stamped to indicate that they are uncontrolled documents.

It shall be the responsibility of the Experiments Task Leader to ensure that those performing the experiments are using the appropriate documents (e.g., experiment plans, measurement plans, and laboratory books).

#### **C.8. CONTROL OF PURCHASED ITEMS AND SERVICES**

The HTR-PROTEUS QA Program shall provide assurances that purchased material, equipment, items, and services conform to procurement document requirements (as described in Section 4). The established measures include provisions for the specification of quality requirements, supplier surveillance, objective evidence of quality, and receiving inspection. The frequency and scope of surveillances depend upon the complexity of the parts and components being manufactured and the intended use.

If formal evaluation(s) and/or negotiation(s) are required as a result of bids or proposals, these activities involve Purchasing and HTR-PROTEUS personnel as appropriate to the scope of the evaluation.

A procurement file will be maintained, of those items that can have a significant impact on the quality of PROTEUS experiments. Items that require a procurement document will be determined by the Project Manager. This document will contain the purchase requisition and the results of analyses performed on the purchased items to characterise the item and show compliance with technical specifications. As appropriate, the document will also include supplier surveillance, receiving inspection, nonconformance reports.

#### **C.9. IDENTIFICATION AND CONTROL OF ITEMS**

The pertinent activity for the HTR-PROTEUS experiments consists of modifying an existing facility and conducting experimental tests. The detailed parts are experiment-specific or one-of-a-kind items and usually do not require unique identification. However, when there is a large quantity of parts or the complexity of the item is such that unique identification is needed, these items are identified in an explicit manner such as the use of serial numbers or unique identification.

The appropriate requirements for identification are contained in the experiment plans, measurement plans, or drawings. These requirements include considerations of proper location of identification markings, use of approved marking materials to preclude adverse quality effects, measures for verification of identity prior to shipment, and records traceable to the materials, parts, and components identification.

#### **C.10. CONTROL OF PROCESSES**

This section is not applicable. There are no special processes associated with the experiments

#### **C.11. INSPECTION**

Inspection can occur at any time during the modification of the PROTEUS facility; the larger portion of inspection activity occurs during the manufacturing of the individual components.

All of the component manufacturing is performed for the PROTEUS facility by outside suppliers. Therefore, the inspection activity associated with the manufacturing process may be delegated to the various suppliers of components and is controlled through the procurement process.

Inspection activity by PROTEUS personnel consists of receiving inspection and those inspections associated with the assembly of the test device. During assembly of the test device, the Task Leader shall identify for inspection of those characteristics that are critical. The status of the inspection operations is documented in a written report. In some cases the inspection results may be stored on a computer disk (e.g., when the inspection equipment works in conjunction with a computer).

## **C.12. TEST CONTROL**

Experiments shall be governed by written and approved experiment and measurement plans. It is the responsibility of the Experiments Task Leader to assure that these plans are prepared and approved by appropriate personnel. Experimental results are recorded in accordance with the plans and reviewed to assure acceptability of the experiment. These results become records and are maintained by the Project Manager.

The Experiments Task Leader has the responsibility for identifying test equipment that requires calibration and for ensuring that the equipment is calibrated prior to use. Calibration requirements will be specified in the measurement plans

The Experiments Task Leader is responsible for the control and approval for use of various computer software programs to be used in gathering and/or analysis of measured data.

Prior to use of computer software the Analysis Task Leader shall categorise the software based upon its intended use. The category level determines the level of review, documentation required, change control, configuration management requirements, and whether verification and validation are needed and to what degree. When validation is required, it is accomplished by comparing code results to either physical data or a validated code designed to perform the same type of analysis. A peer review may be used for code validation if it is the only available means for validating the code. This validation process shall be documented in a report that includes:

- the name and version number of the code;
- a description of the software, including its limitations;
- a description of the method of validation;
- the conditions for which the code has been validated; and
- any conditions for which the code remains invalidated (code segments, run options, and ranges of input that have not been tested).

## **C.13. CONTROL OF MEASURING AND TEST EQUIPMENT**

The Experiments Task Leader has the responsibility for identifying all instruments used during reactor physics experiments or related experimental investigations that require calibration and for describing the type, methods, and intervals of calibration required. Unique identification numbers are assigned to these instruments and they shall be listed in a

'Calibration Log' or laboratory journal and their calibration requirements and status designated.

All instruments requiring calibration are labelled to identify the calibration status. The label includes the identification number, identity of person performing calibration, date of the last calibration, and when the next calibration is due. When labelling is impractical, the items are identified and a record equivalent to the label is maintained by the Experiments Task Leader or a technician.

When instruments are found to be out of tolerance during calibration, the Experiments Task Leader is notified and, in conjunction with the experimenter(s), determines what effect the instrument error had on any data taken since the last calibration.

Calibration of instruments that are related to a specific experiment are the responsibility of the experimentalist and shall be identified in the measurement plans. The method of calibration and results shall be recorded in the experimentalist notebook/journal.

#### **C.14. HANDLING, STORAGE AND SHIPPING**

This section is only applicable to the fuel that will be used during the proposed experiments. As previously stated the fuel was provided by Germany and the shipment was co-ordinated between the government agencies in Germany and Switzerland. It will be stored and handled in accordance with an approved procedure to ensure that the fuel quality is maintained throughout the life of the experiments.

Approved procedures for fuel handling and storage are written in the HTR-PROTEUS "Betriebsvorschriften" (Operating Instructions) and in the "Sicherheitsbericht" (Safety Report).

#### **C.15. INSPECTION, TEST, AND OPERATING STATUS**

Experiments performed at PROTEUS are controlled through the use of experiment plans, measurement plans, and laboratory books (as described in Section C.6). In addition, various operating and experiment logs are maintained by the experimenters that provide the status of activities as they are being accomplished and for documenting the results of the experiment.

#### **C.16. CONTROL OF NONCONFORMING ITEMS**

When a nonconforming item is discovered, a nonconformance report is initiated by the person discovering the nonconformance. The nonconformance report is evaluated and dispositioned by the appropriate design, project, and user personnel.

If at any time during operation of the PROTEUS facility an abnormal event occurs, it shall be termed a disturbance and entered into a separate journal. The disturbance is dispositioned by the Experiments Task Leader and the affected experimentalist if applicable. The disposition is documented in the journal.

### **C.17. CORRECTIVE ACTION**

Conditions adverse to quality of the experimental data shall be promptly reported to the Project Manager and corrected as soon as possible. In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of this corrective action.

### **C.18. QUALITY ASSURANCE RECORDS**

The Project Manager is responsible, in conjunction with the Project Team, for identifying the Quality Assurance Records. Once this identification process has taken place, a listing of the identified Quality Assurance Records becomes a part of the project documentation.

Upon identification of the Quality Assurance Records, it becomes the responsibility of the Project Manager to ensure their maintenance and to control them in such a manner as to prevent damage. On the completion of the HTR-PROTEUS experiments the Project Manager has the final responsibility for determining the method and duration of storage.

### **C.19. AUDITS**

QA audits will be planned and performed by ORNL QA personnel or a team co-ordinated by ORNL QA personnel using ORNL QA procedures for performing audits.

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1.0 PURPOSE

The purpose of this procedure is to establish the requirements and define the practices for assuring that the development and/or use of software by the HTR-PROTEUS Project is accomplished in a controlled and systematic manner.

2.0 SCOPE

The requirements of this procedure apply to computer software that is developed to manipulate data which will be reported as experimental results or to provide guidelines for conducting an experiment.

3.0 REFERENCES

4.0 REQUIREMENTS

The Task Leader shall define the requirements to be applied to the software. Development of new software or changes to existing software shall employ software configuration control to assure a functional and usable end product. The level of control applied, including verification, validation, and documentation, shall be determined by the Task Leader.

5.0 DEFINITIONS

5.1 Purchased or Licensed Software available from commercial sources

5.2 Developed - Software developed for in-house projects

5.3 Modified - Software that was purchased or obtained from some other company or developed earlier at Paul Scherrer Institute (PSI) that has been modified by the developer

5.4 Baseline - Documentation that defines the formally reviewed, agreed-upon configuration of a software product and serves as the basis for further development; baseline documentation can only be changed through formal change control procedures

5.5 Configuration Item - A collection of hardware or software elements and associated documents treated as a unit for the purpose of configuration management

5.6 Developer - The organization or individual who is responsible for the design, development, and implementation of software

APPROVED BY: \_\_\_\_\_

Laboratory Head for Reactor Physics and Systems Engineering

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- 5.7 Software - Computer programs, run modules, procedures, data, and associated documentation concerned with the operation of a computer system
- 5.8 Software Category - A general classification that identifies software in a category based on the effects of a possible software quality failure
- 5.9 Task Leader - Person having overall responsibility for execution of an assigned phase of a project or activity
- 5.10 Testability - Effort required to test software to ensure it performs its intended function
- 5.11 User - An organization or individual responsible for use of the software
- 5.12 Validation - The process of evaluating software at the logical end of the development process of a module or interacting group of modules to ensure compliance with requirements and the accurate execution of functions
- 5.13 Verification - The process of reviewing, checking, or auditing performed during the development of the software to establish and document whether or not the mathematics and program logic have been properly incorporated
- 6.0 RESPONSIBILITIES
- 6.1 Project Leader
  - 6.1.1 Concurs with the software categorization and the levels of review, verification and validation, documentation and configuration control required
- 6.2 Task Leader
  - 6.2.1 Categorizes software according to one of three levels of control
  - 6.2.2 Establishes the requirements for the code
  - 6.2.3 Selects individual(s) or group(s) to perform software development activities
  - 6.2.4 Determines the level of review required for the software development

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6.2.5 Reviews the software development to determine if completeness and accuracy requirements have been met

6.2.6 Determines the level of verification and validation required and ensures that the validation and verification requirements are met

6.2.7 Documents the software development work to the level required

6.2.8 Institutes configuration control to the level required for the task

6.3 Developer

6.3.1 Performs the software design and/or development and provides results to the Task Leader

6.3.2 Resolves reviewer's comments concerning the design and/or development activities

7.0 PROCEDURE

7.1 Categorization of the Software

The Task Leader, with the concurrence of the Project Leader, shall categorize software development and/or software to be used into one of three categories:

Category 1: Software, for which failure could cause the failure of the project

Category 2: Software, for which failure could have a serious effect on the project. This includes software developed or modified for distribution and described as "not fully tested". The recipient accepts the risk that the software may have defects, and the recipient is fully responsible for any use or calculations made using the software

Category 3: Software, for which failure would not have a serious effect on the project. This software, often with a short life, consists of codes that are developed as part of a specific theoretical or experimental task

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7.2 Software Life Cycle - Software development and maintenance activities shall be governed by a systematic approach. This approach shall include distinct activities performed in phases that provide an orderly and traceable progression through the software life-cycle. The phases shall be performed in an iterative or sequential manner. The number of phases and relative emphasis on each phase depends on the nature and complexity of the software.

A cross-reference of the applicable requirements for each category of software is provided in Attachment 1.

7.2.1 Code Requirements - The requirements for the computer code must be established before the code is developed. The technical task to be addressed by the code is defined and the architecture to be used is established. As a minimum the architecture consists of the code structure (number and types of modules), modeling technique (e.g., finite element), and the mathematical techniques (e.g., Monte Carlo) to be used in the modeling.

7.2.2 Reviews - Reviews are required in certain life-cycle phases. Review reports document the participants and their specific responsibilities during the review process, the software being reviewed, the review comments, and their disposition. Comments are retained until they are incorporated into the updated software; if they are not incorporated, they are retained in accordance with the defined category classification. Reviewed software shall be updated and placed under configuration control.

7.2.3 Verification and Validation - Software verification and validation activities are performed to the extent required for the application to ensure that the software adequately and correctly performs all intended functions and does not adversely affect other interdependent software. Software validation should be performed by individuals other than those developing the code. The results of the software verification and validation activities are documented, as required by the program. The documentation should be organized in a manner that allows traceability to both the software requirements and the software design. It should also detail the method of validation used.

Validation shall be accomplished by comparing the code results to either physical data or a validated code designed to perform the same type of analysis. A peer review shall be used for code validation if it is only available means for validating the code. The validation process shall be documented in a report that includes (as a minimum):

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<p>a) the name and version number of the code</p> <p>b) a description of the software, including its limitations</p> <p>c) a description of the validation method</p> <p>d) the conditions for which the code has been validated, and</p> <p>e) any conditions for which the code remains invalidated</p> <p>7.2.4 Documentation - Documentation of the code is performed to the extent required for the application. It can contain some or all of the following elements:</p> <p>a) Comments in the source listing - This is the most basic form of code documentation. The documentation includes, as a minimum:</p> <p style="margin-left: 20px;">a. description of all input parameters</p> <p style="margin-left: 20px;">b. description of how they are input to the code</p> <p style="margin-left: 20px;">c. description of the output from the code</p> <p style="margin-left: 20px;">d. sample input and output, and</p> <p style="margin-left: 20px;">e. code limitations</p> <p>b) Development Methodology Description - The coded model is described and the theory for mathematical and engineering models is described or derived. Symbols used in the exposition of the mathematical models are explicitly related to the nomenclature used in the code itself. The code portions where the mathematical operations occur are also identified. Computer language or languages used in coding the software (Basic, C, Fortran, etc.) should be identified. The exposition of the theory should explicitly display where the input and output parameters occur.</p> <p>c) Software Description - The coded model and its programming are described in such a manner that a thorough understanding of all aspects of the code is afforded to prospective users. The configuration used for the software is described and complete listings of the source code of the software should be available in either printed form or as files on computer storage devices.</p>	

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	<p>d) User's Manual - The user's manual contains a description of all input parameters and how they are input into the code; the output from the code is completely described for each parameter; and sample input is supplied along with output to benchmark and verify the software for the user. All messages printed by the code that indicate abnormalities are explained in detail, and advice to the user concerning appropriate responses is provided. The range of applicability and code limitations is indicated.</p> <p>7.2.5 Configuration Control - Configuration control is implemented to ensure that only authorized changes are made to the software and that authorized users are notified of the changes. A configuration baseline is defined and properly labeled. Changes to the software can then be made only by authorized personnel after the changes have been validated and verified and documented to the appropriate level.</p> <p>7.2.5.1 Configuration identification - A configuration baseline shall be defined at the completion of each major phase of the software development. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recent approved software configuration.</p> <p>7.2.5.2 Labeling system - A labeling system for configuration items shall be implemented. The labeling system shall include the following:</p> <ol style="list-style-type: none"> <li>1. Each configuration item shall be uniquely identified</li> <li>2. Changes to configuration items shall be identified by a revision designation</li> <li>3. The ability to uniquely identify each configuration of the revised software available for use shall be provided</li> </ol> <p>7.2.5.3 Configuration Change Control</p> <p>7.2.5.3.1 Changes to software shall be formally documented and contain a description of the change, the rationale for the change, and the identification of affected baselines. These changes should be distributed to the original distribution list as defined by the Task Leader.</p> <p>7.2.5.3.2 Approved changes shall be made to software baselines only by authorized personnel, as defined by the Task Leader.</p>

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7.2.5.3.3	Software verification shall be performed as necessary to see that the change is appropriately reflected in software documentation and to ensure that requirements traceability is maintained.
7.2.5.3.4	Software validation should be performed as necessary to ensure that the changed software satisfies requirements to the extent possible with available resources.
7.2.5.4	<p>Configuration Status Accounting</p> <p>The information needed to manage a configuration shall be defined and maintained. As a minimum the information shall include the following:</p> <ol style="list-style-type: none"> <li>a. The approved configuration</li> <li>b. The status of proposed changes to the configuration</li> <li>c. The status of approved changes</li> </ol>
7.3	Category 1 Codes
7.3.1	Code Requirements - The code requirements shall be developed by the Task Leader
7.3.2	<p><u>Reviews</u></p> <p>Reviews shall be performed during the code development activity to ensure that the code meets the requirements and that the encoding has taken place properly. The Task Leader shall establish a schedule for the reviews. The Task Leader shall establish the review panel. The review report shall document the participants and their specific responsibilities in the review, the software being reviewed, the review comments, and the disposition of the reviewer's comments. The review reports shall be designated QA Records.</p>
7.3.3	<p><u>Verification and Validation</u></p> <p>Category 1 computer codes shall be verified and validated. Verification shall be performed to ensure that the mathematical models have been properly coded. The Task Leader shall define the process for accomplishing the verification of the code. The review process may be used for code verification. The results of the verification and validation shall be documented and this document shall be a QA Record.</p>

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7.3.4      Documentation

Documentation for Category 1 software shall be at the PSI/TM level or higher. The documentation shall contain a description of code requirements and development methodology, and a description of the software. The code shall also be documented with a user's manual.

7.3.5      Software Configuration Control - Configuration control is required for Category 1 software

7.4        Category 2 Codes

7.4.1      Code Requirements

Code requirements should be established and documented prior to initiating code development. A code requirements document may be developed or appropriate information may be included in the development methodology description and software description documents.

7.4.2      Reviews

Category 2 computer codes should be reviewed during the code development activity. The Task Leader shall determine if reviews are required.

The Task Leader shall also determine who will act as reviewer, the format to be used for the review report, and conduct the review. The Task Leader shall determine if the review report(s) are QA Records.

7.4.3      Verification and Validation

Category 2 computer codes should be verified and validated. The Task Leader shall determine the degree to which the computer code must be verified and validated. The Task Leader shall determine which, if any, verification and validation documents are QA Records.

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7.4.4	<u>Documentation</u>  The Task Leader shall determine the level of documentation. The computer code documentation shall include, as a minimum, a user's manual. This document may be a formal PSI report, a PSI technical memorandum (TM) or another type of internal memorandum.
7.4.5	<u>Configuration Control</u>  Configuration control should be implemented. The Task Leader shall determine what level of configuration control is to be applied. The Task Leader shall define the configuration control system to be used.
7.5	Category 3 Codes
7.5.1	<u>Code Requirements</u>  Code requirements shall be determined by the Task Leader. The Task Leader shall also determine if they are to be documented and what format will be used for the documentation.
7.5.2	<u>Reviews</u>  Review of Category 3 codes is not required. The Task Leader shall determine if a review(s) is to be performed. The reviewer shall be chosen by the code developer.
7.5.3	<u>Verification and Validation</u>  Verification and validation are optional. The Task Leader shall determine if and what level of verification and validation should be performed.
7.5.4	<u>Documentation</u>  Category 3 codes may be documented. The documentation, including development methodology, code validation and verification, and instructions for use, should be carried out in a manner sufficient (in the analyst's judgment) for the level of the activity and may include entry of appropriate material into research notebooks. For small codes, less than 5000 lines of source code, the software may be sufficiently documented by comments in the source listing.

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TITLE: COMPUTER CODES	
7.5.5	<p>Configuration Control</p> <p>Configuration control is not required</p>
7.6	Purchased Software and Software Developed Prior to Issuance of this Procedure
7.6.1	Verification and Validation - Purchased software for main-frames (e.g., Cray, VAX, IBM-3090) and workstations should be validated and verified principally by the vendor with such collaboration by the purchaser as necessary to allow adjustment for any special operating requirements that may exist for the local main-frame or workstation systems.
7.6.2	Documentation - Purchased software should be documented by a user's manual and an example of input and output for the software. Benchmark problems or applications may be supplied with the software.
7.6.3	Change Control
7.6.3.1	Commercially procured software or software developed prior to this standard in Categories 1 and 2 shall be placed under configuration control as defined in Sections 7.2.5. Software in Category 3 may be placed under configuration control as defined by the Task Leader.
7.6.3.2	The Task Leader or Analyst shall (1) evaluate commercially procured software or software developed prior to this standard to determine its adequacy to support software operation and maintenance and (2) identify the activities to be performed and documents that need to be placed under configuration control.
7.6.3.3.	The plans shall address the following:
7.6.3.3.1	User application requirements
7.6.3.3.2	Test plans and test cases required to validate the software for acceptability
7.6.3.3.3	Plans for establishing configuration control of existing software
7.6.3.3.4	User documentation

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TITLE: COMPUTER CODES	

8.0 ATTACHMENT 1 - Summary Requirements for Computer Code

ATTACHMENT 1  
SUMMARY OF REQUIREMENTS FOR  
COMPUTER CODE  
CATEGORIES

**Computer Code Categories**

Software Life Cycle	I	II	III
Code Requirements	Required	Optional	Optional
Review	Required	Optional	Optional
Verification and Validation	Required	Recommended	Optional
Documentation	Development Methodology Description Manual	Software User's Manual	Optional
Configuration Control	Required	Recommended	Optional

<b>HTR-PROTEUS</b>  <b>QA PROCEDURE</b>	PROCEDURE NO: HTR-QA-2
	REVISION 1
	DATE: April 1993
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TITLE: COMPUTER-AIDED ANALYSIS	
1.0	<b>PURPOSE</b> The purpose of this procedure is to establish the requirements and define the practices for assuring that computer-aided analyses, performed by the HTR-PROTEUS Project, are carried out in a controlled and systematic manner.
2.0	<b>SCOPE</b> This procedure applies to computer-aided analyses and covers the documentation, review and approval of this work.
3.0	<b>REFERENCES</b>
3.1	HTR-QA-1 Computer Codes
3.2	HTR-QA-6 Quality Assurance Records
4.0	<b>REQUIREMENTS</b> For computer-aided analyses performed by the HTR-PROTEUS Project, the Task Leader shall define the category type and requirements to be applied to the analyses.
5.0	<b>DEFINITIONS</b>
5.1	Task Leader - Person having overall responsibility for execution of an assigned phase of a project or activity.
5.2	Analyst - The group or individual who is responsible for the analysis, feasibility or design study, and documentation.
5.3	Category 1 - Critical computer-aided analyses that could cause failure of the project. Such analyses shall be documented before distribution outside Paul Scherrer Institute (PSI) unless they are distributed in draft form only and are clearly marked as a draft release.
5.4	Category 2 - Important computer-aided analyses that could have a serious effect on the project. The analyses should be documented. Similar small analyses may be grouped together for documentation purposes.
APPROVED BY: _____ Laboratory Head for Reactor Physics and Systems Engineering	

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TITLE: COMPUTER-AIDED ANALYSIS	
5.5	Category 3 - Scoping computer-aided analyses that could not have a serious effect on the project. These analyses, often with short lives, consist of procedures and techniques that are designed and developed as part of theoretical or experimental research.
5.6	Software - Computer programs, algorithms, run modules, procedures, data, etc., developed to satisfy a specific requirement.
5.7	Validation - The process of evaluating software at the logical end of the development process of a module or interacting group of modules to ensure compliance with requirements and accurate execution of functions.
5.8	Verification - The process of reviewing, checking or auditing performed during the development of the software to establish and document whether or not the mathematics and program logic have been properly incorporated.
6.0	<b>RESPONSIBILITIES</b>
6.1	Project Leader
6.1.1	Concurs with the computer-aided analysis categorization and the levels of review, approval and documentation required.
6.2	Task Leader
6.2.1	Selects individual(s) or group(s) to perform the computer-aided analyses and determines the requirements of the task or activity.
6.2.2	Determines the level of review required for the computer-aided analyses.
6.2.3	Reviews the analyses for completeness and accuracy.
6.2.4	Assures that the analyses are documented and retained.
6.2.5	Controls changes to the analyses.
6.3	Analyst

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6.3.1	Performs computer-aided analyses and provides results to the Task Leader
6.3.2	Resolves reviewer's comments concerning the analyses
7.0	PROCEDURE
7.1	<p>Categorization of the Analysis - The Task Leader, with concurrence of the Project Leader, shall categorize computer-aided analyses into one of three categories:</p> <p>For Category 1 analyses, the results shall be documented in a form appropriate to the importance of the analysis. It is likely that this will be in the form of an PSI/TM report</p> <p>For Category 2 analyses, the results should be documented. Generally, the report format will be less formal than for Category 1 and may take the form of a letter report</p> <p>Category 3 analyses may be documented if the Task Leader determines that the calculations are of sufficient importance to require documentation</p>
7.2	<p>Review and Approval - The Task Leader shall, with concurrence of the Project Leader, determine the review and approval process to be applied to the analyses for Category 1 and 2 analyses</p> <p>Category 1 analyses shall, as a minimum, receive an independent technical review and approval process</p>
7.3	<p>Documentation - The documentation, including development methodology, software, and verification of analysis, shall be carried out in a manner sufficient, in the Analyst's judgment, to permit competent scientific and engineering review. This may range from entry of appropriate material in research notebooks to publication of material in refereed journals, scientific literature, and conference proceedings.</p> <p>Task Leader, with the Project Leader, shall determine the required level of documentation for the analysis. The documentation should include the following information:</p>
7.3.1	Software documentation - Documentation of the software in accordance with the requirements in Reference 3.1 should be given.

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- 7.3.2      Input - A description of all input parameters to the software and their values should be included
- 7.3.3      Output - Archival copies of the significant output should be retained until the completion of the project or until such time indicated by the Task Leader
- 7.3.4      Postanalysis - The computer-aided analysis results may be analyzed, the results postprocessed into graphs or tables, and a descriptive analysis reporting the meaning of the results provided.
- 7.4         Change Control - After the initial analyses have been completed and documented, changes to the computer-aided analyses shall be reviewed, approved, and documented using the same procedure that applied to the original analyses.
- 8.0         ATTACHMENTS  
  
NONE

<b>HTR-PROTEUS</b>  <b>QA PROCEDURE</b>	PROCEDURE NO: HTR-QA-3
	REVISION 1
	DATE: April 1993
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TITLE: EXPERIMENT PLANS	

1.0 PURPOSE

This procedure defines the requirements for preparing, revising, and controlling experiment plans.

2.0 SCOPE

This procedure applies to experimental activities that are performed to establish the physics characteristics for specified core configurations.

3.0 REFERENCES

4.0 REQUIREMENTS

Characteristics to be tested and test methods to be employed shall be specified. Test results that must be documented shall be specified.

5.0 DEFINITIONS

5.1 Experiment Plan - Document prepared to define experiment conditions, test facilities used, and measurement plans needed to obtain data requested in a particular core configuration.

6.0 RESPONSIBILITIES

6.1 Task Leader is responsible for the preparation of experiment plans and for ensuring that the experimental work is carried out in accordance therewith.

6.2 Project Leader is accountable for technical compliance of the experimental activities in response to the data requested.

7.0 PROCEDURE

APPROVED BY: \_\_\_\_\_

Laboratory Head for Reactor Physics and Systems Engineering

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TITLE: EXPERIMENT PLANS	

- 7.1 As a prerequisite to performing the experimental activities encompassed under this procedure the Task Leader shall prepare an experimental plan document for internal review. After completion of the review, approval shall be obtained from the Project Leader.
- 7.2 The experimental plan shall reflect the format shown in Attachment A and shall incorporate the following as applicable:
- a) test conditions to be established
  - b) listing and configuration of requisite test facilities for implementing the experiment(s)
  - c) referencing of measurement plans to be used
- 7.3 The Project Leader shall maintain a list of the original experiment plans and revisions to them. The listing shall contain as a minimum: experiment plan number, date of issue, revision number, author and title.
- Only one official copy of the experimental plans will be controlled. Uncontrolled copies shall be marked "uncontrolled". These are distributed for information only and need not be the current version. Experimental plans shall be maintained as Quality Assurance Records.

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TITLE: EXPERIMENT PLANS	

**ATTACHMENT A**

- 1.0 INTRODUCTION (Purpose / Objectives)
- 2.0 DEFINITIONS
- 3.0 CORE PURPOSE AND DESCRIPTION
- 4.0 PARAMETERS TO BE MEASURED AND TECHNIQUES TO BE USED
- 5.0 TARGET ACCURACIES
- 6.0 REFERENCES



<b>HTR-PROTEUS</b>  <b>QA PROCEDURE</b>	PROCEDURE NO: HTR-QA-4
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TITLE: MEASUREMENT PLANS	

7.2 The measurement plan shall reflect the format shown in Attachment A and shall incorporate the following as applicable:

- a) measurement conditions to be established
- b) listing and configuration of requisite test facilities for implementing the measurement(s)
- c) applicable provisions for calibration of measuring and test equipment
- d) data output required, data acquisition system(s) (including backup, if required) and computer codes for data processing

7.3 The Project Leader shall maintain a list of the original measurement plans and revisions to them. The listing shall contain as a minimum: measurement plan number, date of issue, revision number, author, and title.

Only one official copy of the measurement plans shall be controlled. Uncontrolled copies shall be marked “uncontrolled”. These are distributed for information only and need not be the current version. Measurement Plans shall be maintained as Quality Assurance Records.

8.0 ATTACHMENTS

ATTACHMENT A

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TITLE: MEASUREMENT PLANS	

**ATTACHMENT A**

- 1.0 INTRODUCTION (Purpose / Objectives)
- 2.0 DEFINITIONS
- 3.0 MEASUREMENT PROCEDURE
  - 3.1 INITIAL CONSIDERATIONS
  - 3.2 AUXILIARY MEASUREMENTS
  - 3.3 MAIN MEASUREMENT
- 4.0 DATA STORAGE
- 5.0 ANALYSIS
- 6.0 MEASUREMENT UNCERTAINTY EVALUATION
- 7.0 HARD- AND SOFTWARE LISTING
- 8.0 DOCUMENTATION
- 9.0 RECORDS DISPOSITION
- 10.0 REFERENCES

<b>HTR-PROTEUS</b>  <b>QA PROCEDURE</b>	PROCEDURE NO: HTR-QA-5
	REVISION 1
	DATE: April 1993
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**TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL**

- 1.0      **PURPOSE**  
The purpose of this procedure is to establish the requirements and define the practice for the control and calibration of measuring and test equipment (M&TE) used in the execution of activities affecting quality.
- 2.0      **SCOPE**  
This procedure applies to measuring and test equipment used for generating data in the HTR-PROTEUS project, for items not covered by specific Measurement Plans
- 3.0      **DEFINITIONS**
- 3.1      Accuracy - A measure of the degree to which the actual output of a device approximates the output of an ideal device nominally performing the same function (Reference 4.1).
- 3.2      Measuring and Test Equipment (M&TE)-Devices, systems, or instrumentation used to calibrate measure, gauge, test, inspect, or control in order to acquire research, development, test, or operational data or to determine compliance with design, specifications, or other technical requirements (Reference 4.1)
- 3.3      Calibration - Comparison of M&TE items with reference standards or with M&TE items of equal or closer tolerance to detect and quantify inaccuracies (Reference 4.1).
- 3.4      Precision - The quality of coherence or repeatability of measurement data (Reference 4.2)
- 4.0      **REFERENCES**
- 4.1      IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in the Construction and Maintenance of Nuclear Power Generating Stations, IEEE Standard 498.
- 4.2      Definitions of Terms Used in IEEE Standards on Nuclear Power Generating Stations, IEEE Standard 380-1975.

APPROVED BY: \_\_\_\_\_  
Laboratory Head for Reactor Physics and Systems Engineering

# HTR-PROTEUS QA PROCEDURE

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TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL

## 5.0 REQUIREMENTS

5.1 Measurement and test equipment (M&TE) used in activities affecting quality shall be controlled and calibrated to maintain accuracy within necessary limits.

5.2 M&TE to be utilized shall be of the proper type, range, accuracy, precision, and tolerance

5.3 Calibration of equipment shall occur before initial use and on an established periodic basis. Calibration intervals shall be defined and documented.

5.4 Calibration of standards shall be traceable to National Institute of Standards and Technology (NIST) or Swiss/European equivalent. Traceability to (NSIT) or equivalent shall be documented and verifiable. If no nationally recognized standard exists, the basis of calibration shall be documented.

5.5 The measurement standard shall have a known and accepted accuracy.

5.6 The self-calibration feature on M&TE is not an acceptable alternative to a calibration obtained from independent standards.

5.7 Calibration practices shall be documented. These documents shall address the following items:

- a) indicate relevant M&TE by model name and number
- b) identify measurement standards
- c) identify required environmental conditions, e.g. temperature, humidity, cleanliness, etc.
- d) identify calibration interval
- e) state accuracy limits for calibration
- f) identify the data requirements to be recorded
- g) identify parameters for calibration

5.8 Records shall be maintained for each item requiring calibration. As a minimum, the following information shall be maintained:

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TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL

- a) equipment identification number
- b) equipment suitability evaluation per requirement 5.8b, above
- c) equipment location
- d) reference calibration procedure
- e) calibration interval
- f) equipment calibration history
- g) identify parameters for calibration

Equipment calibration history shall include the following:

- ◆ previous calibration dates
- ◆ as-found condition by date
- ◆ previous calibration results
- ◆ certifier's identification
- ◆ reevaluation of interval and resulting interval change, if appropriate, by date

- 5.9 Personnel performing calibration activities shall be qualified, trained, and indoctrinated appropriate to the scope of work.
- 5.10 Environmental conditions that affect accuracy and stability of the equipment or standards shall be specified and controlled or adequate compensating corrections shall be applied to the calibration results when applicable.
- 5.11 The status of calibrated items will be so indicated on the item or in the records pertaining to that item. When calibration status indicators (decals/tags) are not practical because of size, configuration or environmental limitations, a M&TE logbook or technical notebook, etc. that is specifically traceable to the M&TE, may be used to record the calibration status.
- 5.12 Out-of-calibration devices shall be tagged, segregated, and shall not be used until they have been recalibrated. When measuring and test equipment is found to be out of calibration, the need shall be determined for a documented evaluation of the validity of previous inspection or test results and the acceptability of items previously inspected or tested.
- 5.13 M&TE consistently found to be out of calibration shall be repaired or replaced.

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TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL

- 5.14 A recall system shall be utilized to control the scheduling of calibrations
- 5.15 Calibration may not be required for rulers, tape measures, levels and other such devices if normal commercial equipment provides adequate accuracy.
- 5.16 M&TE shall be properly handled and stored to maintain accuracy and precision
- 5.17 Special calibration requirements shall be listed in the appropriate document, either the operating procedures or measurement procedure
- 6.0 RESPONSIBILITIES
- 6.1 Project Leader
  - 6.1.1 Assures that M&TE applications are reviewed for adequacy
  - 6.1.2 Assures that calibration frequency is established and documented and entered into recall system
  - 6.1.3 Assures that calibration procedures are developed and published
- 6.2 Task Leader
  - 6.2.1 Assures that the calibration recall system is implemented and maintained, and the accuracy of calibration standards are appropriate
  - 6.2.2 Assures that impending calibration activities are scheduled for performance
  - 6.2.3 Appoints Calibrator
  - 6.2.4 Evaluates calibration activities for compliance
  - 6.2.5 Assures maintenance of calibration records
  - 6.2.6 Assures that work is performed by qualified personnel

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**TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL**

- 6.3 Calibrator
  - 6.3.1 Performs calibration
  - 6.3.2 Maintains equipment history file
  - 6.3.3 Notifies Task Leader of any M&TE found to be out-of-calibration
- 7.0 PROCEDURE
  - 7.1 New Equipment Acquisition
    - 7.1.1 As new measurement or test equipment is acquired, responsible technical personnel shall evaluate the equipment to ascertain that it is of the proper type, range, accuracy, precision and tolerance.
    - 7.1.2 Based on equipment specification and intended use, responsible technical personnel categorizes the equipment into one of the following:
      - Category A - “Casual” devices and systems that are not to be calibrated in service
      - Category B - “Routine” devices and systems that are to be included in a calibration recall program on a regular cycle.
      - Category C - “Experimental” devices and systems that are to be calibrated by, or at the direction of, the user as deemed necessary.

This categorization process shall be documented in the M&TE logbook or technical notebook.
    - 7.1.3 The Task Leader, in conjunction with the appropriate experimentalist, then determine M&TE calibration requirements, practice, and interval.
    - 7.1.4 The Calibrator enters the equipment identifier, equipment categorization and the calibration interval into the calibration recall system.
    - 7.1.5 The Calibrator establishes appropriate records for the equipment.
    - 7.2.1 Weekly, the Calibrator determines from the recall system those items requiring calibration.

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TITLE: MEASURING AND TEST EQUIPMENT CALIBRATION AND CONTROL

7.2.2 Periodically, the Task Leader examines the history data base to evaluate and determine the suitability of calibration intervals

7.2.3 When devices are found out of calibration, the Task Leader tags or segregates the devices to ensure they are not used until recalibrated and determines the need to perform a documented evaluation of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.

8.0 RECORDS

8.1 The appropriate equipment history data base is updated and the records are forwarded to the Task Leader, for filing as a Quality Assurance Record.

9.0 ATTACHMENTS

NONE

<b>HTR-PROTEUS</b>  <b>QA PROCEDURE</b>	PROCEDURE NO: HTR-QA-6
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TITLE: QA RECORDS	
1.0	<b>PURPOSE</b> The purpose of this procedure is to define the requirements for the identification, retention, storage, and disposition of Quality Assurance (QA) Records
2.0	<b>SCOPE</b> This procedure applies to records relative to materials, items, activities, and services manufactured, installed, or performed for the HTR-PROTEUS experiments. This procedure includes, but is not limited to, records for the following: <ul style="list-style-type: none"> <li>- technical reports</li> <li>- analytical studies</li> <li>- purchased and externally fabricated materials/items</li> <li>- design activities</li> <li>- construction/modification activities</li> <li>- inspection, test, and calibration activities</li> <li>- general operations</li> </ul> <p>QA Records can include, but shall not be limited to:</p> <ul style="list-style-type: none"> <li>- QA documents such as Experiment Plans, Measurement Plans, QA audit reports, inspections test reports, and measuring and test equipment calibration reports</li> <li>- design documents such as drawings, and specifications;</li> <li>- purchase documents such as requisitions, orders, and change notices</li> <li>- technical outputs such as reports, studies, computer programs, computer tapes, printouts, and data analyses</li> <li>- test documents such as plans, specifications, procedures, and results</li> <li>- laboratory books and operating procedures</li> </ul>
APPROVED BY: _____  Laboratory Head for Reactor Physics and System Engineering	

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TITLE: QA RECORDS	
3.0	REFERENCES
4.0	REQUIREMENTS
4.1	Documents that fall into the category of QA Records (either lifetime or nonpermanent) shall be managed by a records system that identifies, collects, and maintains such documents. The Project Leader shall determine which project documents shall become QA Records.
4.2	A document shall be considered a QA Record after being designated as such. Official designation of a document as a QA Record can be accomplished by stamping, initialing or signing, and dating.
4.3	Records shall be stored in such a manner as to preclude loss, deterioration, and/or destruction.
4.4	Documents that are designated to become QA Records shall be legible, accurate, and completed in a manner appropriate to the work accomplished.
4.5	Records shall be classified as “lifetime” or “nonpermanent” by the Project Leader.
4.6	Lifetime records shall be retained for either the life of the particular item or duration of the task program.
4.7	The retention period of nonpermanent records shall be defined by the Project Leader.
5.0	DEFINITIONS
5.1	Project Leader - Person having overall responsibility for a project.
5.2	Quality Assurance (QA) Records - A completed document which furnishes evidence of the quality of items, activities, or credentials and which has been designated as a QA Record.
5.3	Lifetime Records (L) - Records that meet one of the following criteria: <ul style="list-style-type: none"> <li>a) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;</li> <li>b) those which would be of significant value in demonstrating capability for safe operation;</li> </ul>

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	<p>c) those which would be of significant value in determining the cause of an accident or malfunction of an item; and</p> <p>d) those which would be of significant value in explaining the results from an experiment.</p> <p>Lifetime records are required to be maintained for the life of the particular item, task, program or project.</p> <p>5.4 Nonpermanent Records (NP) - Records required to show evidence that an activity was performed in accordance with the applicable requirements but not needed to be retained for the life of the item/project because they do not meet the criteria for lifetime records.</p> <p>6.0 RESPONSIBILITIES</p> <p>Project Leader</p> <p>6.1 Identifies, designates, and collects documents qualifying as QA Records.</p> <p>6.2 Designates “lifetime” vs “nonpermanent” status of records and determines retention period of nonpermanent records.</p> <p>6.3 Develops and maintains a QA Records Index.</p> <p>7.0 PROCEDURE</p> <p>7.1 Establishing the Record System</p> <p>7.1.1 At the beginning of the HTR-PROTEUS Project the Project Leader shall establish a system for identification, collection, retention, retrieval, and disposition of QA Records. In establishing the system the Project Leader shall consider the following:</p> <ul style="list-style-type: none"> <li>- What records are being generated by this project?</li> <li>- Which records being generated furnish evidence of the quality of the work supporting the project?</li> <li>- How will these records be identified so that they can be retrieved?</li> <li>- What is the appropriate retention time for these records?</li> <li>- How will these records be stored?</li> </ul>

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7.1.2	Records shall be classified and identified as “lifetime” or nonpermanent”. The retention period for nonpermanent records shall be established. A suggested retention period for lifetime records is 12 months after completion of the project.
7.1.3	The Project Leader shall assure that documents are designated as QA Records by initialing or signing, and dating. A document for HTR-PROTEUS shall not be officially designated as a QA Record until all work supporting the development of the document has been completed. Example of completed documents ready for designation as QA Records include issued drawings, issued procedures, issued analytical studies, and issued technical reports.
7.1.4	The Project Leader shall ensure that the QA Records are legible, accurate, and complete.
7.1.5	Computer magnetic media shall be stored in clean facilities free of excessive electrical and magnetic fields. Computer magnetic media shall be duplicated and stored in dual facilities.
7.1.6	QA Records shall be listed on the QA Records Index. The Index shall contain the document title, number, revision level, retention classification, retention period, index entry date, record location(s) and activity of record.
7.2	Storage
7.2.1	In order to preclude deterioration of the records, the Project Leader shall assure the following: <ul style="list-style-type: none"> <li>a) provisions are made in the storage facility to prevent damage from moisture, temperature, and pressure</li> <li>b) records shall be firmly attached in binders or placed in folders or envelopes for storage in file cabinets or for shelving in containers; and</li> <li>c) provisions are made for special processed records (such as radiographs, photographs, negatives, microfile, and magnetic media) to prevent damage from excessive light, stacking, electromagnetic fields, temperature, and humidity.</li> </ul>
8.0	ATTACHMENTS  NONE