

## Quality Assurance Plan for the SCALE Code System

Prepared by

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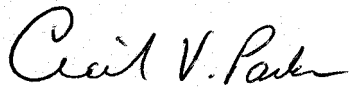
Oak Ridge National Laboratory

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This quality assurance plan provides a statement of the quality policy for the SCALE computational software system and an overview of the quality management system. It is intended to provide employees, users and sponsors with an understanding of the commitment to quality and explain how that commitment is manifested in operations.

Approvals:

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SCALE Project Leader



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## **1 Statement of Quality Policy & Objectives**

In keeping with the UT-Battelle quality policy, as stated in the Oak Ridge National Laboratory (ORNL) Standards Based Management System (SBMS) Quality Assurance Program Description, the SCALE project team has the goal of providing reliable and defect-free products and services to its users in a timely and cost-effective manner, while committing to a continuous quality improvement process that promotes the achievement of excellence.

It is the policy of the SCALE project:

- 1) That all procedures are to be understood and followed.
- 2) That users are promptly informed of issues.
- 3) That safety-significant issues are reported to users and sponsors on a timely basis.
- 4) That all staff members strive to deliver defect-free software with validated performance.
- 5) That all staff members subscribe to the Continuous Integration model of software development, where the production code base is maintained in a shippable, defect-free state at all times.

With this overall policy in mind, the SCALE project has set the following specific quality objectives:

- 1) Registration to the ANSI/ISO/ASQ Q9001-2008 standard.
- 2) Responses to user inquiries are provided within 5 days of receipt.
- 3) Responses to user discrepancy reports are provided within 48 hours of receipt.
- 4) Safety-significant issues are reported to users and sponsors within 48 hours of that determination.

## 2 Introduction

Since 1970 ORNL has provided the Atomic Energy Commission, now the Nuclear Regulatory Commission (NRC), with programming and technical assistance in the analysis of nuclear fuel facility and package (cask) designs. Beginning in 1976, the NRC Office of Nuclear Material Safety and Safeguards (NMSS) began an effort in cooperation with the NRC Office of Research (RES) to fund ORNL to develop an easy-to-use computational system known as SCALE that would provide a needed tool for evaluating criticality, shielding, and thermal aspects of nuclear fuel facility and/or spent fuel cask designs. SCALE provides a comprehensive, verified and validated, user-friendly tool set for criticality safety, reactor physics, radiation shielding, radioactive source term quantification, including radiation spectra, decay heat, nuclide generation and decay, as well as sensitivity and uncertainty analysis. Verified and validated nuclear data are also distributed with SCALE. These data include multi-group and continuous-energy cross-section data, activation and decay libraries, material composition data, and cross-section covariance data.

The maintenance and development of SCALE is also cosponsored by the Department of Energy (DOE) Packaging Certification Program (PCP), the DOE Nuclear Criticality Safety Program (NCSP), and other sponsors. SCALE has become an increasingly popular computational system and is used around the world by nations with nuclear science programs. The code system is used by government regulatory agencies and contractors, national laboratories, utilities, nuclear fuel vendors, spent fuel storage and transportation cask vendors, and universities.

In July 1980, the initial version of SCALE was made available to the Radiation Safety Information Computational Center (RSICC) at ORNL. This system was packaged and released by RSICC as CCC-288/SCALE 0. Subsequent additions and modifications resulted in the following releases: CCC-424/SCALE 1 in 1981; CCC-450/SCALE 2 in 1983; CCC-466/SCALE 3 in 1985; CCC-545/SCALE 4.0 in 1990; SCALE 4.1 in 1992; SCALE 4.2 in 1994; SCALE 4.3 in 1995; SCALE 4.4 in 1998; SCALE 4.4a in 2000; and CCC-725/SCALE 5 in 2004; CCC-732/SCALE 5.1 in 2006; CCC-750/SCALE 6.0 in 2009; and CCC-785/SCALE 6.1 in 2011. SCALE is also distributed by the Organization of Economic Cooperation and Development (OECD) Nuclear Energy Agency (NEA) Data Bank center in Paris, France and the Research Organization for Information Science and Technology (RIST) Nuclear Code Information Services (NUCIS) in Tokai, Japan.

With the release of SCALE 4.0 in 1990, a Quality Assurance (QA) Plan and a Configuration Management Plan were developed and implemented. The configuration-controlled version of SCALE is maintained and controlled in accordance with these plans by the SCALE staff within the Reactor and Nuclear Systems Division (RNSD) at ORNL. Newly developed modules and approved revisions or corrections to existing modules are subsequently released to RSICC for distribution. With each release, updated documentation is provided as revisions to the SCALE Manual. The documentation 1) describes the theory for solving the problem, 2) provides a discussion on the range of applicability, and 3) provides a thorough user input guide and example problem set.

Throughout the history of the SCALE project there has been a commitment to generate software that is reliable, accurate, and easy to use. Testing and validation have been performed for various modules and data libraries and documented in published reports that are available on the SCALE website. **However, users should independently submit the software to their own testing program prior to use, in accordance with their site or program requirements.**

## 3 Quality Management System

### 3.1 The SCALE QA Program

It is the purpose of the SCALE QA Program to provide the processes, controls, and infrastructure to ensure the satisfaction of users and program sponsors, and to promote continuous improvement.

The SCALE QA Program is based on the applicable requirements of the following reference sources:

- 10 CFR 830 Subpart A, *Quality Assurance Requirements*,
- ORNL Standards Based Management System (SBMS) Quality Assurance Program Description,
- DOE Order 414.1D, *Quality Assurance*, and
- ANSI/ISO/ASQ Q9001-2008, *Quality Management Systems – Requirements*.

Additionally, this QA Program is compatible with ASME NQA-1-2008, Quality Assurance Requirements for Nuclear Facility Applications.

A set of crosswalks of this document to these standards is provided in Section 0.

With this QA Plan, the SCALE QA program has set the specific objective of striving for ANSI/ISO/ASQ Q9001-2008 compliance and registration to that standard. This QA Plan supersedes the previous documented QA Plan in SCALE-QAP-005, Rev. 3.

The SCALE QA Plan provides specific guidance to all SCALE project staff as to which QA requirements must be met for SCALE operations, identifies who is responsible for meeting those requirements, and details how those requirements are to be accomplished. Among other goals, the processes described in this plan are intended to ensure that:

- routine maintenance and further enhancement of the SCALE code system is performed in a controlled, documented, and traceable fashion;
- qualified personnel perform the SCALE system maintenance and enhancement;
- changes and enhancements are tested, documented, and implemented in accordance with established procedures;
- necessary verification and validation activities are performed; and
- public releases of the code to users are conducted in accordance with established procedures.

The scope of this QA Plan is limited to those activities required to maintain the operational integrity of the SCALE configuration controlled version, and verification and validation activities, which serve to qualify the SCALE system. This plan does not address application of the system to specific user needs; applications of SCALE fall under the specific quality requirements of each user. As such, the end-users of SCALE are responsible for ensuring that the SCALE software is both applicable to and sufficient for their specific uses, and for implementation of any additional quality requirements mandated by their respective organizations or oversight authorities.

### 3.2 Graded Approach

The QA Program uses a graded approach to apply QA requirements to work activities in order to match controls to items and activities consistent with their importance to the achievement of mission objectives: development of defect-free software that has validated performance.

To establish the UT-Battelle Quality Category, the SCALE system was evaluated in accordance with the SBMS General Software Grading Level Table and determined to be Moderate Impact. The activity is evaluated against the ten criteria of 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and UT-Battelle and ORNL SBMS procedures and QA requirements. The resulting QA Plan (this document) must then include those controls necessary to assure reliability and repeatability in SCALE work activities. The subsequent sections of this QA Plan reflect the results of that evaluation and determination.

Any relevant changes to the SBMS Subject Area: Software Quality Assurance and its grading process are evaluated during the scheduled management review (Section 4.6) and, if necessary, will result in modification to this plan and/or its referenced procedures.

### **3.3 Outsourcing**

Code or data submitted by subcontractors, such as students, postdocs, visiting researchers, etc., is reviewed and verified by a SCALE developer who is assigned to execute the quality management process and integrate the new feature into the configuration-controlled version of SCALE. No subcontractor-produced code is utilized in SCALE until it has undergone the same QA process as team-produced code.

### **3.4 Documentation Requirements**

#### **3.4.1 General**

The documents requiring control on the SCALE project are:

- ORNL/TM-2005/39: the set of user manuals containing instructions for using the SCALE system. The SCALE Software Quality Assurance (SQA) Coordinator controls a master set under the SCALE configuration management system. Uncontrolled copies of the operating manuals are issued to external users as part of distribution of the SCALE code system.
- SCALE-CMP-001: SCALE Configuration Management Plan (plus supporting CM procedures listed in Section 9.5). The SCALE Project Leader controls and issues to a controlled distribution that includes SCALE staff.

#### **3.4.2 Quality Assurance Plan**

This quality plan is reviewed on an annual basis for applicability to the current development and maintenance activities in SCALE and for compliance with governing procedures, such as the ORNL SBMS. Updates to the plan are generated by the SCALE Project Leader and reviewed by appropriate line managers as well as the organizational quality manager. Revisions to this plan are distributed to the SCALE development staff and then archived in the Integrated Document Management System (IDMS).

#### **3.4.3 Control of Documents**

Documentation of the SCALE code system, including the user manual, is version controlled and stored in an electronic tracking system.

Instructions and procedures, such as those developed to support the SCALE Configuration Management Plan, are prepared, reviewed and approved by the SCALE Project Leader, or a designated alternate, in accordance with the RNSD Records Management Plan.

The SCALE Project Leader will make decisions on any additional documents that are recommended for control and will assign responsibility for control of documents to SCALE staff, as necessary.



#### **3.4.4 Control of Records**

SCALE project records are identified and maintained in accordance with the RNSD Records Management Plan. The record categories determined by the SCALE Project Leader to be appropriate for consideration as records, in consultation with the Nuclear Science and Engineering Directorate (NSED) Records Officer, are identified in Section 0. The SCALE Project Leader is responsible for identification of completed records and forwarding them to the assigned records custodian for entry into the master and duplicate files. In addition, SCALE QA records are indexed within each category list in Section 0.

## **4 Management Responsibility**

The members of the SCALE Leadership Team recognize and accept their responsibilities to focus on users, set quality policy and objectives, provide proper planning, and assign appropriate roles and responsibilities to achieve the quality objectives.

### **4.1 Management Commitment**

The SCALE Leadership Team is committed to ensuring the quality of SCALE, and takes responsibility for ensuring the full satisfaction of users and sponsors.

The SCALE Leadership Team meets several times per year to plan strategic activities and review the SCALE quality policies and their implementation. The Leadership Team is committed to the above-stated Quality Policy and objectives and to this plan as the means to achieve those objectives.

### **4.2 User Focus**

It is the mission of the SCALE project to develop, deploy, and support a quality-assured computational toolkit that advances the state-of-the-art and exemplifies ease-of-use in a scalable architecture beginning with fundamental physical data and providing validated analysis capabilities for criticality safety, radiation shielding, radiation source terms, and reactor physics.

The SCALE project team is committed to meeting or exceeding the expectations of its sponsors and end users. The project management has the responsibility to ensure that proper focus is maintained on user satisfaction and accomplishes this through regular reviews of user requirements and feedback.

### **4.3 Quality Policy**

The SCALE Leadership Team is responsible for setting the quality policy, and reviewing the policy on an annual basis to ensure that it remains appropriate. The policy is documented in this QA Plan, which is required reading for all new SCALE project staff members, and as it is revised.

### **4.4 Quality Planning**

The SCALE Leadership Team recognizes that achieving high quality requires proper planning.

The Leadership Team is responsible for:

- determining the overall quality objectives for the project and its periodic product releases, and managing the activities of the development teams that fulfill the project objectives.
- overseeing the quality management system and updating/revising the system should the need arise.
- ensuring that revisions to the SBMS subject area on software QA trigger a reevaluation of this plan against those requirements.

The SCALE Leadership Team is responsible for communicating QA requirements, policy, and objectives to the development teams and fostering a culture of quality in every aspect of the teams. Communication of expectations of quality is achieved through email, verbal, or posted communications as well as team meetings and a developers' forum.

## **4.5 Roles and Responsibilities**

The staff responsibilities for SCALE are as follows:

### **4.5.1 SCALE Project Leader**

The following responsibilities are delegated to the SCALE Project Leader:

- work with RNSD line supervision to prepare budgets, and ensure that adequate staffing is available, make work assignments, and assure that work is carried out on a timely schedule and within budget;
- review and approve QA and work plans and supporting SCALE procedures;
- report program status on a routine basis;
- authorize the SCALE system releases;
- approve changes to the system; and
- assure the overall quality of the SCALE system as the representative of this Quality Management System.

The SCALE Project Leader has the authority and responsibility to request that work be stopped where quality or safety requirements are not being met, and to contact the appropriate level of management to obtain remedial actions to resolve problems. For subtasks within SCALE that have assigned task leaders, the Project Leader delegates authority to those task leaders as appropriate, while retaining responsibility for the SCALE system.

### **4.5.2 SCALE Leadership Team**

The SCALE Leadership Team consists of the SCALE Project Leader, line managers, program managers, and developers as designated by the SCALE Project Leader. The Leadership Team meets regularly to discuss the current status and make programmatic and managerial decisions regarding SCALE.

### **4.5.3 Quality Program Manager**

The Quality Program Manager supports the RNSD Director in assuring that an appropriate QA program is implemented for SCALE by

- evaluating the SCALE project with the Project Leader to determine applicable QA requirements,
- assisting the Project Leader in planning that identifies quality assurance controls appropriate to the work,
- approving this QA Plan and revisions thereto,
- interfacing with other ORNL divisions and UT-Battelle organizations on quality-related matters, and
- conducting surveillance on behalf of the Project Leader and higher management to verify compliance with established requirements.

The Quality Program Manager has the authority, independence, and organizational freedom to identify quality-related problems, initiate and evaluate solutions to those problems, and to verify implementation of solutions. The Quality Program Manager has the authority and responsibility to request that work be stopped where quality requirements are not being met, and to contact the appropriate level of management to obtain remedial actions to resolve quality problems. The Quality Program Manager reports at the same

organizational level as the highest line manager directly responsible for performing quality-related activities. This structure avoids any compromise of quality due to requirements such as cost and schedule.

#### **4.5.4 SQA Coordinator**

The SQA Coordinator is responsible for the implementation, protection, and maintenance of the SCALE software system.

#### **4.5.5 VALID Coordinator**

The (Verified, Archived Library of Input and Data) VALID Coordinator is responsible for ensuring the quality of input files and data in the VALID archive.

#### **4.5.6 SCALE Staff**

The SCALE staff members include Team Leaders, Developers, Reviewers, and Analysts. The staff is responsible for conducting work in accordance with this QA Plan and procedures, and with SCALE technical and administrative procedures.

#### **4.5.7 SCALE Teams**

SCALE Teams are organized to coordinate work activities within given technical areas. The SCALE Leadership Team organizes the teams, designates the team members, a convener for each team, and a SCALE Leadership Team point of contact. Each team meets independently several times per year to plan and coordinate work activities. The Teams report their progress to the SCALE Leadership Team as well as to other Teams. The Teams will be organized such members from different work areas are included on multiple teams to improve communication and coordination between work areas.

### **4.6 Management Review**

This QA Plan is reviewed on a yearly basis for continuing suitability and effectiveness by the SCALE Leadership Team. Any needed changes to the QA Plan and its referenced procedures are initiated at that time.

#### **4.6.1 Review input**

The management review utilizes some or all of the following information to make informed decisions about the continued suitability and effectiveness of the QA Plan:

- Bug log,
- User complaints and suggestions,
- Helpline issues,
- Team leader and team member feedback,
- Any relevant assessment results,
- New or revised requirements from sponsors,
- Changes to SBMS that affect the project,
- Project metrics.

#### **4.6.2 Review output**

The minutes of the management review are stored as a record per the RNSD Records Management Plan. In addition, the review process can generate some or none of the following outputs:

- New quality policy statements,

- New quality objectives,
- Recommended modifications to the QA Plan and/or its referenced procedures,
- Corrective actions,
- New metrics.

The Leadership Team is responsible for making any decisions necessary to act upon recommendations of the QA Plan review.

## **5 Resource Management**

### **5.1 Provision of Resources**

The SCALE Project Leader commits the necessary staff members and associated resources to maintain the QA Plan, improve its effectiveness, and meet user requirements. This is accomplished through budgeting for the necessary full-time staff members; employing the services of any external resources and subject matter experts when needed; and outsourcing services for certain processes (e.g., assistance with internal assessment). Evaluating the adequacy of resources is routinely addressed in the Leadership Team meeting process.

The RNSD at ORNL provides the staff to support the SCALE system. The SCALE system is primarily supported by funding from both NRC and DOE projects, as well as other interim sponsors.

Quality Assurance support to SCALE is provided by the Quality Program Manager. When requested, QA activities are reported to sponsors by the SCALE Project Leader.

### **5.2 Human Resources**

General human resources support is provided by the ORNL Human Resources Directorate, per the SBMS requirements in the Human Resources Management System.

SCALE management and staff members are qualified by experience, education, and training to perform their assigned responsibilities. The qualifications of each person are documented on Biographical History sheets, which are maintained in the SCALE QA records system. Identification of training appropriate to assure that staff proficiency is adequately maintained is a joint responsibility of the SCALE Project Leader, the SCALE Leadership Team, and each staff member. SCALE staff members are required to be knowledgeable of and conduct all work in accordance with this QA Plan. The SCALE Project Leader has an additional responsibility to assist the staff in obtaining necessary UT-Battelle training, attendance at pertinent technical conferences where professional training is provided, and any needed task-specific training. Records of task-specific training are maintained by the SQA Coordinator.

Training and qualification of QA audit personnel are completed in accordance with the requirements of procedure QSSD-QMS-001, *Qualifying Auditors and Certifying Lead Auditors*.

Candidates must be approved by the Project Leader a documented résumé must be recorded in an archival system before a team member can perform work under this QA Plan.

### **5.3 Infrastructure**

The NSED maintains a Facility Management Plan, which captures space, equipment and support service requirements from the SCALE project team. This plan is updated on a yearly basis. Any changes to facility infrastructure needs are facilitated by the RNSD Operations Manager.

The SCALE Project Leader decides what resources (hardware and software) are required to support the project objectives, with input from the staff members. Requests are reviewed by the SCALE Project Leader and approved with the consensus of the SCALE Leadership Team. The System Administrator, provided by ORNL IT, maintains the computing infrastructure (including the SCALE cluster and backup systems) with patches, updates to OS and compilers, electronic tracking systems, configuration management, and support tools.

The SCALE project uses an electronic system to provide a collaborative development infrastructure, including features for the development backlog, quality assurance workflow, source code version control, document control, bug tracking, helpline, and project management metrics.

An automated build and test environment is implemented to provide continual testing with multiple test suites on all supported platforms (Linux, Mac, and Windows).

#### **5.4 Work Environment**

Recognizing that the responsibility and authority for attainment of quality reside with the line organization, each SCALE team member is responsible for providing work practices, goals, and employee interactions that promote an environment where communication is open, barriers to performance are identified and corrected, and a safe and productive workplace exists. Each team member has the obligation and organizational freedom to identify and report to management any current or potential deficiency that may have a detrimental effect on quality, safety, cost, or schedule so that appropriate corrective action may be initiated.

SCALE work activities are accessible (at reasonable times and under the coordination of the Project Leader) during normal working hours for purposes of audit, surveillance, inspection, or visit by authorized representatives of UT-Battelle or SCALE sponsors.

SCALE team activities, including office ergonomic policies, are governed by ORNL SBMS and relevant Facility Use Agreements (FUA).

## **6 SCALE Development**

The overall process of SCALE development is documented in this section and is illustrated in Section 9.2.

### **6.1 Planning**

SCALE is provided to end users on a periodic basis as a product release. The SCALE Leadership Team performs high-level planning of features and releases based on the needs of SCALE sponsors, end users, and ORNL management.

The SCALE Leadership Team meets frequently to plan SCALE development activities. Activities are assigned to the development teams through an electronic tracking system, which is typically supplemented with email or oral communication. The development teams are responsible for low-level design and detailed work planning, which is documented in the electronic tracking system.

### **6.2 Determination and Review of Requirements**

SCALE is constantly under development, and new requirements from sponsors and users are continually brought forward and implemented under direction of the SCALE Project Leader. End user requirements are typically gathered by direct feedback via SCALE users at ORNL, the email helpline, the electronic notebook, and communication during training courses and conferences. Sponsors' requirements are defined in Project Work Scope documents and milestones. High-level requirements are entered into the electronic tracking system in the product backlog.

The SCALE Leadership Team is responsible for reviewing user requirements for completeness and suitability and working with the Development Teams to set milestones and deliverables for fulfilling those requirements. The Leadership Team is also responsible for reviewing and mitigating any risks associated with the development activities.

### **6.3 User Communication**

SCALE project management uses the following communication tools to notify users of changes to the SCALE system:

- E-mail notices are sent to local ORNL users whenever a change has been implemented in the production version of SCALE.
- Interim change orders are sent to the distribution center on a quarterly basis to notify them of all changes that have been implemented in the ORNL production version of SCALE.
- External users of the SCALE system are notified of corrections and updates via e-mail notices and/or the SCALE Newsletter as deemed appropriate by the Project Leader.

The Project Leader, with concurrence of the Leadership Team, decides when sufficient changes have been made to issue a new version of SCALE. At the Project Leader's discretion, important changes may be made available to external users before a new version of SCALE is issued. These changes are posted as updates on the SCALE website or provided to select users as a beta release.

### **6.4 Design and Development**

Each feature of SCALE is planned, designed, implemented, verified, and validated using a graded approach following the process detailed below.



#### **6.4.1 Design and development planning**

The Project Leader provides high-level feature requests to the development teams. The development teams produce the development plan including low-level design and testing strategies needed to implement the feature and verify and/or validate its performance. High-level development, test, and documentation planning is performed by the development team and recorded in the electronic tracking system for review and approval by the Project Leader prior to initialization of development activities. The Project Leader will request additional input from other staff members as deemed appropriate for the given task. The Project Leader will ensure effective communication between the team members and make clear assignments of responsibility.

#### **6.4.2 Design and development inputs**

Development teams draw upon the high-level feature requests and supporting information as well as their knowledge of the existing system and its architecture, subject to development staff resources. The requirements for verification and validation will be well defined. Feature and testing requirements shall be complete, unambiguous, and not in conflict with each other.

#### **6.4.3 Design and development outputs**

The design of the feature is documented in flow diagrams and in the electronic tracking system, as appropriate. The feature and associated tests are implemented to demonstrate the functionality of the feature to meet the design requirements. Updates to the user documentation are provided to document the theory and use of the new feature. All outputs are recorded in the electronic tracking system for review.

#### **6.4.4 Design and development review**

At suitable stages throughout the feature implementation, reviews of the design and development will be performed as requested by the SCALE Project Leader and the development team to evaluate the ability of the feature to meet the design requirements, identify and problems and propose corrective actions. Participants in the reviews shall include those with specific expertise in the area of design and development being reviewed. The SCALE Project Leader will designate the development activity complete only after a final review.

#### **6.4.5 Design and development verification & validation**

Verification and/or validation of each feature are performed using a graded approach based on the complexity of the feature at a level determined to be appropriate by the SCALE Project Leader. Results of all verification or validation activities are documented in the electronic tracking system and reviewed for technical adequacy and appropriateness by at least one independent reviewer with the required qualifications as assessed by the Project Leader.

#### **6.4.6 Control of design and development changes**

The SCALE system (hardware, software and documentation) is under control of a configuration management system as described in SCALE-CMP-001, *Configuration Management Plan for the SCALE Code System*, plus supporting configuration management procedures.

In accordance with the Configuration Management Plan and procedures, modifications or additions to the SCALE system must be submitted to the Project Leader for authorization to proceed. Changes must be tested and documented, independently reviewed, and approved by the Project Leader prior to incorporation into the production version of SCALE.

## **6.5 Purchasing**

The SCALE project follows the ORNL procedures and policies documented in SBMS for purchasing any items needed to support SCALE development, including, if appropriate, Quality Significant Review of purchasing requirements and acceptance testing.

Specific evaluation and acceptance tests shall be designated for other than off-the-shelf items or software that are obtained from sources outside of ORNL. Results of such tests will be documented and kept with the project file relating to the software.

## **6.6 Release Processes**

Periodic releases of SCALE occur when the Project Leader, with concurrence of the Leadership Team, determines that sufficient new features have been implemented, tested, and documented to warrant either a beta release to selected recipients or a general release.

### **6.6.1 Control of releases**

Control of releases is provided by the SCALE Configuration Management Process, which makes use of procedures as listed in Section 9.4, List of Procedures. All development activities are required to follow these procedures.

Each release will contain comprehensive user documentation that describes all features as well as instructions for installing, building, and executing the software. A suite of test problems and a mechanism for executing the tests and verifying the results shall be provided to ensure the operability of the software and data.

### **6.6.2 Validation of release processes**

The SCALE Project Leader and Leadership Team continually monitor the quality of the output product as measured by defect reports, user feedback, and the test procedures. Any deficiency in the processes is addressed by the Leadership Team, who makes needed changes to the SCALE development process and referenced procedures.

### **6.6.3 Identification and traceability**

A software repository and electronic tracking system label each source code revision, so that changes can be traced and, if needed, reverted.

The software self-reports its version information to users whenever it is run, including its build date and execution date. Each version is traceable to the revision where the change, testing, and review are documented.

### **6.6.4 User property**

On occasion users seeking technical support or guidance will send input files to the SCALE team for error tracing or help purposes. These files may contain confidential design data, and are treated per the SBMS subject area "Proprietary Information and Protected CRADA information." It is the responsibility of the user to properly categorize and mark any data that need to be protected.

### **6.6.5 Preservation of product**

The handling, storage, and shipping of SCALE software and supporting documentation to users is performed by RSICC, which is the DOE software distribution center. The approved SCALE baseline

version and accompanying documentation are delivered to RSICC to prepare code packages for external distribution. The software and documentation packages are handled, stored, and shipped according to RSICC operating procedures. RSICC may provide SCALE to additional centers for further distribution. SCALE users are notified that they are responsible for their specific uses of the SCALE system.

## **6.7 Control of Test and Monitoring Equipment**

The development and production code and data are monitored for quality with a series of tests, which run on a regular schedule. The tests are version controlled in the repository system. Designated testing machines (running Windows, Mac OS, and Linux) are maintained as test environments. The test log records the machine, date, and time of each test execution such that any discrepancies can be precisely determined and resolved.

## **7 Measurement, Analysis, and Improvement**

In order to ensure that quality goals are met and user satisfaction is achieved, several project management and quality indicators, as well as user feedback, are monitored. The SCALE Project Leader and the Leadership Team are responsible for implementing, reviewing, and updating appropriate monitors and metrics to detect quality problems.

### **7.1 User Satisfaction**

Users can submit error reports and questions through email helpline requests, posts in the online electronic notebook, or through direct contact at training sessions and conferences. Issues are entered into the tracking system and are monitored to resolution.

As metrics of user satisfaction, the following metrics are tracked:

- the number of email helpline issues addressed each month,
- the number of user support and bug tickets opened and closed during the month, and
- the number of users licensing the package.

### **7.2 Monitoring Quality in Development**

Routine execution of the test suites on the development and production code bases is the primary quality monitor. Ongoing system corrections, improvements, and tests are addressed per the procedures in SCALE-CMP-001. Pre-release Beta testing may be performed by internal and external users, at the discretion of the Project Leader.

### **7.3 Monitoring Development Processes**

The SCALE Leadership Team and development team leads are responsible for monitoring development process activities, identifying problem areas, and implementing appropriate corrective actions. Informal process monitoring is achieved by daily management interactions with staff. More formal monitoring is achieved by periodic assessment and audit, both internal and external. The test harness is monitored to ensure that all defined tests continually produce the expected results. As new features are added, sufficient tests are defined to continually assess the performance of each feature. As features are updated or removed, the test suite is updated accordingly.

#### **7.3.1 Internal assessment**

The SCALE Project Manager assures that sufficient internal assessments are conducted to confirm that this SCALE QA Plan is adequately implemented, and that any identified problems are corrected. The SCALE system is routinely assessed by developers and analysts as a byproduct of conducting analyses for users.

Assessments of the SCALE configuration management system are periodically conducted in accordance with SCALE-CMP-001, SCALE Configuration Management Plan. These assessments are conducted by technically qualified SCALE staff members. The results are reported, and corrective actions are taken when necessary.

Follow-up action is taken by the SCALE Project Leader and Leadership Team, when necessary, based on the results of the assessments. Corrective actions resulting from such assessments are documented, tracked, completed, and verified in accordance with Section 3 of this QA Plan.

### **7.3.2 Independent assessment**

Assessments conducted within RNSD but outside the SCALE Project Team fall into the independent assessment category. These may be conducted by RNSD senior management, the RNSD Quality Manager, or by other qualified staff with concurrence from RNSD management. ORNL requires that QA audits and surveillances will be performed in accordance with established procedures. Personnel leading QA audits are certified by UT-Battelle as described in SBMS. QA audits are planned and scheduled to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

Assessments conducted by organizations external to the RNSD also fall into the independent assessment category. These may be scheduled and conducted by such organizations as: ORNL Performance and Quality, Independent Oversight, the Department of Energy, Nuclear Regulatory Commission, and other sponsors of work activities. Such assessments are coordinated, scheduled, conducted and reported by the assessing organization.

The SCALE Project Leader implements corrective actions, when necessary, based on the results of independent assessments. Corrective actions resulting from such assessments are documented, tracked, completed and verified in accordance with Sections 7.6.2 and 7.6.3 of this plan.

## **7.4 Control of Nonconforming Product**

Bugs, errors, and code- and data-level issues are handled per the SCALE Procedure for Discrepancy Reports, SCALE-CMP-004. Corrective actions resulting from the identification of a nonconforming product are documented, tracked, completed, and verified in accordance with Sections 7.6.2 and 7.6.3 of this plan.

## **7.5 Analysis of Data**

User communications via email helpline, online forums, or verbal communications are analyzed by SCALE staff members and any identified issues, requirements, or improvements are passed on to the SCALE Project Leader and Leadership Team for consideration. Bugs are analyzed to determine the source cause and are handled per the SCALE Procedure for Discrepancy Reports, SCALE-CMP-004.

Failures of the test suites are analyzed, traced to root cause, and addressed per the SCALE Procedure for Discrepancy Reports, SCALE-CMP-004.

## **7.6 Improvement**

### **7.6.1 Continual improvement**

The SCALE team is committed to continual improvement in the quality of the product and the processes by which it is developed and tested. Improvement of the SCALE system is an ongoing process which is controlled through the Configuration Management Plan and supporting procedures. Changes to the SCALE system are evaluated, tested, and approved prior to incorporation into the configuration-controlled version of SCALE. Improvements to project management and QA Plan processes are the responsibility of the Project Leader and Leadership Team.

### **7.6.2 Corrective action**

Significant conditions adverse to quality are identified and corrective action taken to avoid repetition of problems. Procedures documented in the ORNL Performance Based Management System and Issues

Management Subject Area are used for identifying, reporting, and correcting quality problems. The SCALE code system is controlled and documented through the Configuration Management Plan, SCALE-CMP-001.

Should any reportable occurrences be identified, they will be reported and tracked in accordance with the most current ORNL SBMS procedure for occurrence reporting, consistent with DOE Manual M231.1-2.

*Significant software errors* are defined here as those program or data errors that appear to allow proper execution of the software, with no warning or error message, yet provide results that are:

- Inconsistent with the evaluated nuclear data or the theory models applied in the codes, and
- Judged to be of potential significance to operational safety (e.g., potential  $k_{\text{eff}}$  error greater than 1%)

Significant software errors are reported to end-users and program sponsors according to SCALE-CMP-004.

Corrective actions resulting from surveillance and audit or other assessment activity are tracked by the Project Leader and the Program Quality Manager.

### **7.6.3 Preventive action**

Issues identified by internal testing or assessment are addressed on a timely basis by SCALE management. If necessary, code patches are issued and further testing may be done to verify the effectiveness of the action.

## 8 References

- 10 CFR 830 Subpart A, *Quality Assurance Requirements*
- ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications, Part 1* (from former NQA-1)
- ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications, Part 2* (from former NQA-2) Subpart 2.7
- SBMS Quality Assurance Program Description
- DOE Manual M231.1-2, *Occurrence Reporting and Processing of Operations Information*
- DOE Order 414.1D, *Quality Assurance*
- ANSI/ISO/ASQ Q9001-2008, *Quality Management Systems*

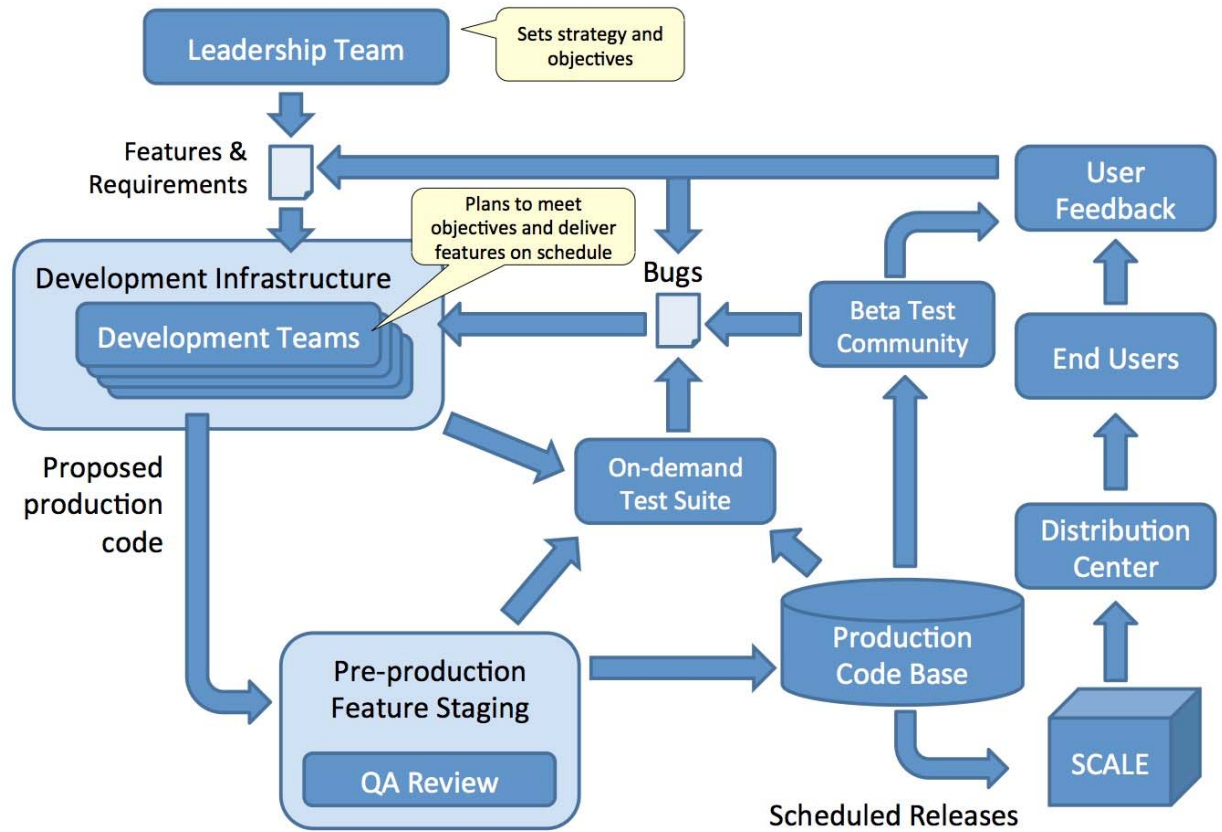
## 9 Appendices

### 9.1 List of Acronyms

DOE	Department of Energy
NCSP	Nuclear Criticality Safety Program
NRC	Nuclear Regulatory Commission
ORNL	Oak Ridge National Laboratory
PCP	Package Certification Program
QA	Quality Assurance
QAP	Quality Assurance Plan
QMS	Quality Management System
RSICC	Radiation Safety Information Computational Center
SBMS	Standards-Based Management System



## 9.2 SCALE Development Process



### 9.3 Functional Responsibility Matrix

P = Prepare/Perform A = Approve I = Input R = Review S = Surveillance D = Distribute	Project Leader	SCALE Leadership Team and SCALE Teams	VALID Coordinator	SQA Coordinator	Quality Program Manager	Distribution Center
Documents/Actions						
QA Plan	P, A, D, S	I, R	I, R	I, R	P, A, S	
Configuration Mgmt. Plan and Procedures	P, A, D, S	I, R	I, R	I, R	R, A	
V&V Plan	P, A	I, R	I, R	I, R	R, A	
QA Records	A	I, R		P	S	
Documentation	R, A	I, P, R		R	S	D
Software	A	I, P, R				D
Data	A	I, P, R				D
Technical Reviews	P	P, I			S	
Design Requirements	I, R, A	I, P			S	
V&V Tests	I, R, A	I, P			S	
Configuration Control List	R, A	I, R		P	S	
Software Archive				P	S	
Software Changes	P, R, A	P, R		P	S	
VALID Changes	R, D	P, R	P, R, A	P	S	
Change Documents	R, A	P, R, I		P	S	
Biographical Sheets	R, S, A	P, I		P		
Newsletter/Website	I, R, A, D	I		P		

## 9.4 List of Procedures

Procedure	Document Title
<b>Configuration Management Plan for the SCALE Code System</b>	SCALE-CMP-001
<b>SCALE Procedure for Discrepancy Reports</b>	SCALE-CMP-004
<b>SCALE Procedure for Verified, Archived Library of Input and Data (VALID)</b>	SCALE-CMP-012
<b>SCALE Procedure for Feature Changes</b>	SCALE-CMP-013

## 9.5 Records Schedule

### QA RECORDS CATEGORY LIST

QA Records		Retention Period <sup>(1)</sup>	Master File Point <sup>(2)</sup>	Duplicate File Point <sup>(3)</sup>
Abbreviation	Category			
AU	Audit/Surveillance Reports	L	5700, N322	ERS
BHS	Biographical History Sheets	L	5700, N322	ERS
CCV	Computer Code Verification/Validation Documentation: Sample Problems Verifications, V&V Plans and Reports	L	CDE	BU
CMP	Configuration Management Plan and Procedures	L	5700, N322	IDMS
CODE	SCALE Computer Code	L	CDE	RSICC, BU
CSDC	SCALE Code Documentation	L	5700, N322	RSICC
DIST	QA Document Distribution and Control	L	5700, N322	ERS
QAP	SCALE QA Plan	L	5700, N322	IDMS
SCL	SCALE Change Log	L	CDE	BU
VALID	VALID Report	L	CDE	BU
TRA	Training Records	L	5700, N322	ERS

<sup>(1)</sup> **L** - Lifetime (Determined by records turnover schedule);      **N** - Non-permanent

<sup>(2)</sup> **CDE** (Collaborative Development Environment software)

<sup>(3)</sup> **ERS** (ORNL Electronic Records System)

**IDMS** (Integrated Document Management System)

**BU** (Automated File Back Up System)

## 9.6 Crosswalks to source requirements

### 9.6.1 ANSI/ISO/ASQ Q9001-2008

<b>ANSI/ISO/ASQ Q9001-2008 Requirement</b>	<b>Section in this document</b>
<b>4 Quality management system</b>	<b>3</b>
<b>4.1 General requirements</b>	<b>3.1</b>
<b>4.2 Documentation requirements</b>	<b>3.4</b>
<b>5 Management responsibility</b>	<b>0</b>
<b>5.1 Management commitment</b>	<b>4.1</b>
<b>5.2 Customer focus</b>	<b>4.2</b>
<b>5.3 Quality policy</b>	<b>4.3</b>
<b>5.4 Planning</b>	<b>4.4</b>
<b>5.5 Responsibility, authority and communication</b>	<b>4.4, 4.5</b>
<b>5.6 Management review</b>	<b>4.6</b>
<b>6 Resource management</b>	<b>0</b>
<b>6.1 Provision of resources</b>	<b>5.1</b>
<b>6.2 Human resources</b>	<b>5.2</b>
<b>6.3 Infrastructure</b>	<b>5.3</b>
<b>6.4 Work environment</b>	<b>5.4</b>
<b>7 Product realization</b>	<b>0</b>
<b>7.1 Planning of product realization</b>	<b>6.1</b>
<b>7.2 Customer-related processes</b>	<b>6.2, 6.3</b>
<b>7.3 Design and development</b>	<b>6.4</b>
<b>7.4 Purchasing</b>	<b>6.5</b>
<b>7.5 Production and service provision</b>	<b>6.6</b>
<b>7.6 Control of monitoring and measuring equipment</b>	<b>6.7</b>
<b>8 Measurement, analysis and improvement</b>	<b>0</b>

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<b>8.1 General</b>	0
<b>8.2 Monitoring and measurement</b>	7.2, 7.3
<b>8.3 Control of nonconforming product</b>	7.3
<b>8.4 Analysis of data</b>	7.5
<b>8.5 Improvement</b>	7.6

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## 9.6.2 DOE Order 414.1D “Quality Assurance”

<b>DOE Order 414.1D Quality Assurance Criteria</b>	<b>Section in this document</b>
<b>Criterion 1— Management/Program</b>	3, 0
<b>Criterion 2— Management/Personnel Training and Qualification</b>	5.2
<b>Criterion 3— Management/Quality Improvement</b>	0
<b>Criterion 4— Management/Documents and Records</b>	3.4
<b>Criterion 5— Performance/Work Processes</b>	0
<b>Criterion 6— Performance/Design</b>	6.4
<b>Criterion 7— Performance/Procurement</b>	3.3, 6.5
<b>Criterion 8— Performance/Inspection and Acceptance Testing</b>	3.3, 6.6, 6.7, 7.1, 7.2
<b>Criterion 9— Assessment/Management Assessment</b>	7.3.1
<b>Criterion 10— Assessment/Independent Assessment</b>	7.3.2

### 9.6.3 ASME NQA-1-2008

ASME NQA-1-2008 Requirement	Section in this document
<b>1 Organization</b>	3.1, 4.5
<b>2 Quality Assurance Program</b>	3.1
<b>3 Design Control</b>	6.4
<b>4 Procurement Document Control</b>	6.5
<b>5 Instructions, Procedures and Drawings</b>	3.4
<b>6 Document Control</b>	3.4
<b>7 Control of Purchased Items and Services</b>	3.3, 6.5
<b>8 Identification and Control of Items</b>	6.6.3
<b>9 Control of Special Processes</b>	N/A
<b>10 Inspection</b>	3.3, 6.2, 6.4.4, 6.5
<b>11 Test Control</b>	6.4.5, 6.4.6, 6.6.1, 6.7
<b>12 Control of Measuring and Test Equipment</b>	6.7
<b>13 Handling, Storage and Shipping</b>	6.6.5
<b>14 Inspection, Test, and Operating Status</b>	0
<b>15 Control of Nonconforming Items</b>	7.4
<b>16 Corrective Action</b>	7.6.2, 7.6.3
<b>17 Quality Assurance Records</b>	3.4.4
<b>18 Audits</b>	7.3



#### 9.6.4 ORNL SBMS QAP Description

<b>ORNL SBMS QAP Description</b>	<b>Section in this document</b>
<b>1 Software Project Management and Quality Planning</b>	0
<b>2 Software Project Risk Management</b>	6.2
<b>3 Software Configuration Management</b>	6.4.6
<b>4 Software Procurement and Supplier Management</b>	6.5
<b>5 Software Requirements</b>	6.2
<b>6 Software Design and Implementation</b>	6.4
<b>7 Software Failure Analysis (Software Safety)</b>	6.7, 7.4, 7.5
<b>8 Software Verification and Validation</b>	6.4.5, 6.6.2
<b>9 Software Problem Reporting and Corrective Action</b>	7.4
<b>10 Software Training</b>	5.2