Second Target Station Project
Configuration and Quality Level Determination

CONFIGURATION LEVEL (from Step 6 of Instructions)**:**

1 Serious ☐, 2 Important ☐, 3 Routine ☒, 4 Special ☐

QUALITY LEVEL (from Step 9 of Instructions):

1 Serious ☐, 2 Important ☒, 3 Routine ☐

Purpose—this form is used with conjunction with S01020000-PR0001-R01, *Configuration Management Procedure for the Second Target Station Project*, and *S01020000-PC0001, General Policy on Engineering Practices,* to document a Configuration Level Determination, and S01030200-PR0002, *Quality Level Determination Procedure,* to document a Quality Level Determination. Upon completion of the Determinations and approval signatures, the form is a Quality Record and submitted into EDRM.

CAUTION: This blank form is a Controlled Document. A printed or downloaded copy may not be the current revision. Check the STS document control system before each use.

Document Number	S04080600-QAI10000-R00
Grading of	QIKR Motion System (excluding the Shutter and Maintenance Shield)
WBS Description	Applies to all QIKR Motion WBS components except the Shutter and Shield

Approvals:	
L2 WBS Manager[4]	
Neutronics[3,4]	
Radiation Safety Officer[3,4]	
Lead Engineer[2]	Danielle Wilson — Digitally signed by Danielle Wilson Date: 2024.10.22 14:37:32 -04'00'
Systems Engineering and Integration Lead[2]	David Anderson — Anderson, David Digitally signed by Anderson, David Date: 2024.10.23 09:45:25 -04'00'
Quality Representative[1,2]	Tim Gregory — Timothy Gregory Digitally signed by Timothy Gregory Date: 2024.10.22 15:51:49 -04'00'
ES&H Representative[1,2]	Steve Trotter — Steven M. Trotter Digitally signed by Steven M. Trotter Date: 2024.10.23 16:31:37 -04'00'
Configuration Control Manager[1,2]	Van Graves — Digitally signed by Van Graves Date: 2024.10.24 07:38:58 -04'00'
Configuration Authority[5]	

[1]Required approval for Configuration Level Determination
[2]Required approval for Quality Level Determination
[3]Optional approval for Configuration Level Determination
[4]Optional approval for Quality Level Determination
[5]Required approval for Configuration Level 1 Determination

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Configuration Level Determination

Table 1. CM SSC Checklist

Category	Criteria	Yes	No
Mission Critical SSCs, Software and Firmware	Could failure of the SSC result in more than one week loss of facility operation?	☐	☒
	Could failure of the SSC prevent one or more neutron beamlines from operating for more than 6 months?	☐	☒
	Could failure of the SSC prevent three or more neutron beamlines from operating for more than 3 weeks?	☐	☒
Environmental Protection SSCs	Could failure of SSC result in exceeding regulatory limits or involve significant cleanup cost?	☐	☒
Costly SSCs	Could failure of SSC result in a repair cost of more than $5 million?	☐	☒
Safety Management System Work Processes	Is the process or procedure for fire protection, maintenance, radiation protection, worker safety, hazardous materials handling, pressure safety, quality management, integrated safety management, accelerator beam safety, emergency preparedness procedures, or evacuation of accelerator before startup (or similar)?	☐	☒
Worker and Public Safety SSCs	Could failure of the SSC result in a loss of life to a worker or member of the public?	☐	☒
Key Performance Parameter SSCs	Does the functionality of the SSC affect the STS's ability to achieve a Key Performance Parameter (KPP)?	☐	☒
PPS	Is the SSC a Personnel Protection System (PPS)?	☐	☒
CECs	Is the SSC a Credited Engineering Control (CEC)?	☐	☒
Fire Protection	Is the SSC a fire protection system?	☐	☒
CA Discretion	Does the Configuration Authority classify the SSC as a Configuration Managed System Structure or Component (CM SSC) for any other reason?	☐	☒

If any row in Table 1 is marked "yes", then the SSC is a Configuration Managed System, Structure, or Component (CM SSC) and is a "Level 1 – Serious" grade per the Graded Approach Matrix shown in Table 2 of *S01020000-PC0001 General Policy on Engineering Practices*.

Configuration Level Determination (Continued)

Table 2. CI Checklist

Criteria	Yes	No
Is the SSC biological radiation shielding?	☐	☒
Is the SSC a Shutter or shutter control?	☐	☒
Is the SSC a High Energy Pressure Systems (see policy on pressure and vacuum systems as listed in *S01020000-PC0001 General Policy on Engineering Practices)*?	☐	☒
Is the SSC an emission control system?	☐	☒
Is the SSC a load bearing structure?	☐	☒
Is the SSC a lifting fixtures or device?	☐	☒
Does the CCM classify the SSC as a CI for another reason?	☐	☒

If any row in Table 2 is marked "yes", then the SSC is a Configuration Item (CI) and is a "Level 2 – Important" grade per the Graded Approach Matrix shown in Table 2 of *S01020000-PC0001 General Policy on Engineering Practices*.

If all rows in both matrices are marked "no", then the SSC is a "Level 3 – Routine" grade per the Graded Approach Matrix shown in Table 2 of *S01020000-PC0001 General Policy on Engineering Practices* unless the CCM designates the SSC as "Level 4 – special."

The Graded Approach Matrix shown in Table 2 of *S01020000-PC0001 General Policy on Engineering Practices* indicates the level of review and approval required for all configuration levels.

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Quality Level Determination

Table 3 Quality Level

Risk Type	Level 1: Serious Consequences	Level 2: Important	Level 3: Routine
Accelerator Safety Envelope 1 ☐ 2 ☐ 3 ☒	Violating the Accelerator Safety Envelope, including through affecting STS or SNS credited engineered controls	Adverse effect on credited engineered controls or administrative controls providing safety margin	No potential for adverse effects on the safety envelope or credited controls
Comments:			
Radiological Concerns 1 ☐ 2 ☐ 3 ☒	Onsite impacts to large numbers of persons or major impacts to the environment	Considerable potential onsite impacts to people or the environment, but only minor offsite impacts	Minor onsite and negligible offsite impacts to people and the environment.
Comments:			
Environmental 1 ☐ 2 ☐ 3 ☒	Environmental damage that could exceed regulatory limits or involve significant cleanup costs	Moderately adverse impact on the environment, with moderate remediation and cleanup costs	Minor impact on the environment, with minimal cleanup costs or remediation effort
Comments:			
Health & Safety 1 ☐ 2 ☐ 3 ☒	Death or total disability or severe adverse impact on the health or safety of a worker or member of the public	Injury or illness requiring hospitalization, temporary or partial disability	Minimal impact on health and safety, such as injury or illness requiring minor supportive treatment but not hospitalization
Comments:			
Conformance to Laws, Regulations, DOE and Other Requirements 1 ☐ 2 ☐ 3 ☒	Significant potential for noncompliance with state and federal laws and regulations, or nonconformance to DOE requirements, or an STS Safety Assessment Document	Some potential for nonconformance to ORNL or STS procedures, or minor noncompliance with state and federal laws and regulations	Minor or no nonconformance with established STS or SNS management practices
Comments:			
User Impact or Availability 1 ☐ 2 ☒ 3 ☐	Significant adverse impact to an SNS or STS user or an important impact to multiple users	Important adverse impact to a user but not affecting other users	Negligible impact to users
Comments: Assume low risk of a failure that affects both beam paths or causes a long duration shut down			

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Risk Type	Level 1: Serious Consequences	Level 2: Important	Level 3: Routine
Functional 1 ☐ 2 ☒ 3 ☐	Significant adverse impact to achieving or maintaining key facility performance and reliability goals	Important adverse impact to a major system or component, but not blocking STS from key performance goals	Potential for negligible impact to any facility system, component, or task
Comments: This follows along with the "User Impact…" rating and reasoning			
Financial 1 ☐ 2 ☐ 3 ☒	Significant unintended costs above contingency or delay of project funding for more than 1 year	Some unintended cost above contingency, or delay in funding for some major activities for a year or two	Unintended costs within available contingency, or delay in funding for non-critical activities for a short period of time
Comments:			
Schedule 1 ☐ 2 ☐ 3 ☒	Significant schedule delays, especially those affecting the STS critical path	Moderate schedule delays that do not impact critical path	Minor schedule delays that do not impact other schedules
Comments:			
Sponsor / Public Concern or Confidence 1 ☐ 2 ☐ 3 ☒	Significant concern about loss of confidence in the project or facility by the sponsor or the public	Minor concern about reduced confidence	Little or no concern about reduced confidence
Comments:			
Personnel Resources 1 ☐ 2 ☐ 3 ☒	Significant unavailability of trained and qualified personnel to perform critical activities required for project, facility, or activity completion	Personnel are available but need additional training or qualification to perform needed supportive project or facility activities	Personnel are available and only need site or facility specific training in order to perform project or facility activities
Comments:			
Material Resources 1 ☐ 2 ☐ 3 ☒	Significantly limited availability of critically required materials or equipment in order to meet the project or facility technical or operational goals	Limited availability of specialized materials or equipment needed, but alternates are available with reduced capabilities	Needed materials and equipment are available from multiple suppliers
Comments:			
Supplier Availability 1 ☐ 2 ☒ 3 ☐	Significant lack of capable suppliers of critically required items or services needed for project or facility completion	Limited availability of capable suppliers of required items or services needed for project or facility completion	Multiple capable suppliers of needed items or services required for project or facility completion
Comments: Some components may need to come from specific suppliers, but most won't			

Risk Type	Level 1: Serious Consequences	Level 2: Important	Level 3: Routine
Availability of Alternate Technology	No alternate technology is available that could provide the level of performance required by the project or facility	Alternate technology is available but at potentially reduced performance from that required of the project of facility	Alternate technology is available and capable of providing the required level of performance required of the project of facility
1 ☐			
2 ☒			
3 ☐			
Comments: The technology used is not exotic, though certain components need specific accuracies/resolutions			

If any risk type is marked "1", the QL is 1.
If there is no risk type marked "1" but there is at least one "2" marked, the QL is 2.
If all risk types are marked "3", the QL is 3.

Table 4. Requirements for Work Activities Chosen Based on Quality Levels

Level 1: Rigorous	Level 2: Disciplined	Level 3: Normal
Quality Assuring		
Configuration Managed Structures, Systems and Components (CM SSCs): • Design Requirements Review, Conceptual Design Review, Preliminary Design Review, Final Design Review[1] • Drawing approvals by the Configuration Authority	Configuration Items (CIs): • Formal Final Design Review[1], informal Conceptual Design Review, informal Preliminary Design Review • Drawing approvals by the Configuration Control Manager	Non-CM or CI: • Informal Final Design Review. Optional Conceptual and Preliminary Design Reviews • Drawing approval by Designated Design Authority
• Complete design documentation and records[1]	• Adequate and appropriate design documentation	• Minimal documentation
• Certified or similar documented worker qualifications, shown on MIP[1]	• Qualified personnel assigned, shown on MIP[1]	• Knowledgeable personnel used
• Acceptance Checklist (ACL) created[1] • Failure Mode and Effects Analysis (FMEA) Created[1]	• ACL or equivalent created[1] • FMEA or equivalent created[1]	• ACL optional but encouraged dependent upon component interactions • FMEA not required
• Vendor qualification and QA representation during evaluation of competitive responses[1]	• Vendor qualification (completed QA/QC Questionnaire minimum)[1]	• Follow ORNL SBMS Purchase Goods and Services procedure for procurement of non-quality significant items
• Approved documented procedures for activity[1]	• Procedures as needed IAW ORNL SBMS	• Procedures other than ES&H as needed IAW ORNL SBMS
Quality Controlling		
• Manufacturing Inspection Plan (MIP) required[1]	• MIP required[1]	• MIP not required
• Formal inspection and testing per MIP[1]	• Tests and inspections of critical attributes[1]	• Normal receipt inspection only, plus any ES&H requirements

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Level 1: Rigorous	Level 2: Disciplined	Level 3: Normal
• ACL completed by STS[1] • FMEA completed by STS[1]	• ACL or equivalent completed by STS[1] • FMEA or equivalent completed by STS[1]	• ACL optional but encouraged dependent upon component interactions • FMEA not required
• Comprehensive oversight and assessment activities[1]	• Oversight by general management assessments and Quality assessments	• Oversight performed by line supervision
• Controlled measuring and test equipment (M&TE)[1]	• Controlled M&TE[1]	• Controlled M&TE not required but encouraged dependent upon component interactions
• Suspect Counterfeit Item (S/CI) detection, control, prevention by supplier[1]	• S/CI detection and control by supplier[1]	• S/CI detection and control at STS
• Identification and control of items	• Uniquely identify items and control as needed[1]	• Best commercial practices for item controls (e.g., catalog number)
• Maintain items to prevent damage or loss	• Store items in appropriate conditions to prevent damage or loss	• Prevent loss

[1]ESH&Q representatives approvals are required.

List Attachments:

No attachment, but per discussion on Oct.22, 2024 with David Anderson, Tim Gregory, and Danielle Wilson, vendor qualification will not be required because 1) these assemblies will be built in-house and 2) the components within the assemblies are either COTS components or machined parts that will not require specialized shops to produce.

Document Number & Revision	Title

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Instructions

1. Enter new document number in “Document Number” box. This number is obtained from the Enterprise Document and Records Management (EDRM) System.
2. Enter the applicable element, Structure, System, or Component (SSC), activity, task, etc. title in the “Grading Of” box.
3. Enter the applicable WBS Description (e.g., Instruments/CHESS/Optics).
   Note: Enter any additional blank lines and position title of any additional affected disciplines requiring approval in the blank lines under the Approvals column.

Configuration Level Determination

4. Determine if the Structure, System, or Component (SSC) is a Configuration Management SSC level 1 using Table 1. Then mark the corresponding Category box as yes or no as determined by the discussion.
   - If any row in Table 1 is marked “yes”, the SSC is a “Level 1 – Serious” grade.
5. Determine if the SSC is a Configuration Item by answering the questions in Table 2. Then mark the corresponding Category box as yes or no as determined by the discussion.
   - If any row in Table 2 is marked “yes”, then the SSC is a Configuration Item and is a “Level 2 – Important” grade.
   - If all rows in both Tables 1 and 2 are marked “no”, then the SSC is a “Level 3 – Routine” grade; unless the CCM designates the SSC as “Level 4 – Special” based upon S01020000-PC0001, *General Policy on Engineering Practices*.
6. Enter the corresponding Configuration Level box as 1, 2, 3, or 4 as determined by the evaluation at the top of the form under “Configuration Level”.

Quality Level Determination

7. Determine the Quality Level (QL) using Table 3. In each row, or Risk Type, discuss the implications for the WBS component or SSC being graded. Then mark the corresponding Risk Type box as 1, 2, or 3 as determined by the discussion. Add any comments, thought processes, topics to follow up, etc., to the Comment Section under each Risk Type to capture any discussion used in the decision-making process, as determined wanting to be captured by the evaluation team.

   NOTE: Where the discussion of risk (=hazard x probability of occurrence) is important to choosing the QL of a row in the table, the calculation and its assumptions are either attached to this form or added to the “Comments” portion of the applicable Risk Type.

8. Examine the marked boxes.
   - If there is even a single row marked “1”, the QL is 1.
   - If there is no row marked “1” but there is at least a “2” marked, the QL is 2.

- If all rows are marked “3”, the QL is 3.

9. Enter the corresponding Quality Level box as 1, 2, or 3 as determined by the evaluation at the top of the form under “Quality Level”.
10. Decide the Proportionate Actions by using Table 2, which uses general terms for which more specific procedures and other documents may be available at the time of the QL determination.
11. Make a list of actions to be taken because of the grade assigned, that are important to completing the WBS, SSC procurement, or other activity being graded. Be as specific as possible considering the status of the graded item and the circumstances. Attach the list to this form.
12. Route the completed form and any attachments generated as a result of the determination to the responsible WBS manager and approval disciplines listed on Page 1 of this form for signature.
13. When all approvals are obtained, send the completed form (along with any attachments) to the Second Target Station document control center or EDRM System.