CONFIGURATION LEVEL (from Step 6 of Instructions):

1 Serious \Box , 2 Important \Box , 3 Routine \boxtimes , 4 Special \Box

QUALITY LEVEL (from Step 9 of Instructions):

1 Serious \Box , 2 Important \Box , 3 Routine \boxtimes

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	S04080500-QAI10001
Grading of	QIKR Beam Monitor
WBS Description	Applies only to the Beam Monitor in the QIKR Detector WBS

Approvals:	
L2 WBS Manager ⁴	
Neutronics ^{3,4}	
Radiation Safety Officer ^{3,4}	
Lead Engineer ²	Danielle Wilson
Systems Engineering and Integration Lead ²	David Anderson
Quality Representative ^{1,2}	Tim Gregory
ES&H Representative ^{1,2}	Steve Trotter
Configuration Control Manager ^{1,2}	Van Graves
Configuration Authority ⁵	

¹Required approval for Configuration Level Determination

²Required approval for Quality Level Determination

³Optional approval for Configuration Level Determination

⁴Optional approval for Quality Level Determination

⁵Required approval for Configuration Level 1 Determination

Configuration Level Determination

Table 1. CM SSC Checklist

Category	Criteria	Yes	No
Mission Critical SSCs,	Could failure of the SSC result in more than one week loss of		\boxtimes
Software and	facility operation?		
Firmware	Could failure of the SSC prevent one or more neutron beamlines		\boxtimes
	from operating for more than 6 months?		
	Could failure of the SSC prevent three or more neutron		\boxtimes
	beamlines from operating for more than 3 weeks?		
Environmental	Could failure of SSC result in exceeding regulatory limits or		\boxtimes
Protection SSCs	involve significant cleanup cost?		
Costly SSCs	Could failure of SSC result in a repair cost of more than \$5		\boxtimes
	million?		
Safety Management	Is the process or procedure for fire protection, maintenance,		\boxtimes
System Work	radiation protection, worker safety, hazardous materials		
Processes	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	Could failure of the SSC result in a loss of life to a worker or		\boxtimes
Safety SSCs	member of the public?		
Key Performance	Does the functionality of the SSC affect the STS's ability to		\boxtimes
Parameter SSCs	achieve a Key Performance Parameter (KPP)?		
PPS	Is the SSC a Personnel Protection System (PPS)?		\boxtimes
CECs	Is the SSC a Credited Engineering Control (CEC)?		\boxtimes
Fire Protection	Is the SSC a fire protection system?		\boxtimes
CA Discretion	Does the Configuration Authority classify the SSC as a		\boxtimes
	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		No
Is the SSC biological radiation shielding?		\boxtimes
Is the SSC a Shutter or shutter control?		\boxtimes
Is the SSC a High Energy Pressure Systems (see policy on pressure and vacuum systems as		\boxtimes
listed in S01020000-PC0001 General Policy on Engineering Practices)?		
Is the SSC an emission control system?		\boxtimes
Is the SSC a load bearing structure?		\boxtimes
Is the SSC a lifting fixtures or device?		\boxtimes
Does the CCM classify the SSC as a CI for another reason?		\boxtimes

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.

Quality Level Determination

Table 3 Quality Level

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

Risk Type	Level 1: Serious	Level 2: Important	Level 3: Routine
	Consequences		
Functional	Significant adverse impact to	Important adverse impact	Potential for negligible
1 🗆	achieving or maintaining key	to a major system or	impact to any facility
2 🗆	facility performance and reliability goals	component, but not blocking STS from key	system, component, or task
3 🖂		performance goals	Lask
Comments:		P	
Financial	Significant unintended costs	Some unintended cost	Unintended costs within
1 🗆	above contingency or delay of	above contingency, or delay	available contingency, or
2 🗆	project funding for more than 1	in funding for some major	delay in funding for non-
3 🛛	year	activities for a year or two	critical activities for a short period of time
Comments:			pendu of time
Schedule	Significant schedule delays,	Moderate schedule delays	Minor schedule delays that
1 🗌	especially those affecting the	that do not impact critical	do not impact other
2 🗆	STS critical path	path	schedules
3 🖂	1		
Comments:			
Sponsor / Public	Significant concern about loss	Minor concern about	Little or no concern about
Concern or	of confidence in the project or	reduced confidence	reduced confidence
Confidence	facility by the sponsor or the		
1 🗆	public		
2 🗆			
3 🖂			
Comments:			
Personnel	Significant unavailability of	Personnel are available but	Personnel are available
Resources	trained and qualified	need additional training or	and only need site or
1 🗆	personnel to perform critical	qualification to perform	facility specific training in
2 🗆	activities required for project, facility, or activity completion	needed supportive project or facility activities	order to perform project or facility activities
3 🖂		of facility activities	of facility activities
Comments:			
Material	Significantly limited	Limited availability of	Needed materials and
Resources	availability of critically	specialized materials or	equipment are available
1 🗆	required materials or	equipment needed, but	from multiple suppliers
2 🗆	equipment in order to meet	alternates are available	
	the project or facility	with reduced capabilities	
3 🖂	technical or operational goals		
Comments:			
Supplier	Significant lack of capable	Limited availability of	Multiple capable suppliers
Availability	suppliers of critically required	capable suppliers of	of needed items or
1 🗆	items or services needed for	required items or services	services required for
2 🗆	project or facility completion	needed for project or facility completion	project or facility completion
3 🖂			
	irrently the only source, but if ILL	closes the monitors would like	alv be made elsewhere

Risk Type	Level 1: Serious	Level 2: Important	Level 3: Routine
	Consequences		
Availability of	No alternate technology is	Alternate technology is	Alternate technology is
Alternate	available that could provide	available but at potentially	available and capable of
Technology	the level of performance	reduced performance from	providing the required
1 🗆	required by the project or	that required of the project	level of performance
2 🗆	facility	of facility	required of the project of facility
3 🖂			lacinty
Comments:		-	•

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 Review¹ Drawing approvals by the Configuration Authority 	 Configuration Items (CIs): Formal Final Design Review¹, 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 records¹ 	 Adequate and appropriate design documentation 	 Minimal documentation 	
 Certified or similar documented worker qualifications, shown on MIP¹ 	 Qualified personnel assigned, shown on MIP¹ 	Knowledgeable personnel used	
 Acceptance Checklist (ACL) created¹ Failure Mode and Effects Analysis (FMEA) Created¹ 	 ACL or equivalent created¹ FMEA or equivalent created¹ 	 ACL optional but encouraged dependent upon component interactions FMEA not required 	
 Vendor qualification and QA representation during evaluation of competitive responses¹ 	 Vendor qualification (completed QA/QC Questionnaire minimum)¹ 	Follow <u>ORNL SBMS Purchase</u> <u>Goods and Services procedure</u> for procurement of non-quality significant items	
 Approved documented procedures for activity¹ 	 Procedures as needed IAW ORNL SBMS 	 Procedures other than ES&H as needed IAW ORNL SBMS 	
	Quality Controlling		
 Manufacturing Inspection Plan (MIP) required¹ 	• MIP required ¹	MIP not required	
• Formal inspection and testing per MIP ¹	 Tests and inspections of critical attributes¹ 	 Normal receipt inspection only, plus any ES&H requirements 	

Level 1: Rigorous	Level 2: Disciplined	Level 3: Normal
 ACL completed by STS¹ FMEA completed by STS¹ 	 ACL or equivalent completed by STS¹ FMEA or equivalent completed by STS¹ 	 ACL optional but encouraged dependent upon component interactions FMEA not required
 Comprehensive oversight and assessment activities¹ 	 Oversight by general management assessments and Quality assessments 	 Oversight performed by line supervision
 Controlled measuring and test equipment (M&TE)¹ 	 Controlled M&TE¹ 	 Controlled M&TE not required but encouraged dependent upon component interactions
 Suspect Counterfeit Item (S/CI) detection, control, prevention by supplier¹ 	 S/CI detection and control by supplier¹ 	S/CI detection and control at STS
 Identification and control of items 	 Uniquely identify items and control as needed¹ 	 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

¹ESH&Q representatives approvals are required.

List Attachments:

Document Number & Revision	Title

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.
- 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.