1.0 SCOPE

Computational modeling and simulation (CM&S) have been used throughout the product life cycle to assess the technical performance, safety and effectiveness of medical devices. This procedure provides guidance on the process to perform a risk-informed credibility assessment of computational models through verification and validation (V&V) activities that are commensurate with the associated model risk. This procedure has been developed in alignment with the process outlined in the ASME VVUQ 40 2018 standard, *Assessing Credibility of Modeling Through Verification and Validation: Application to Medical Devices*.

2.0 APPLICATION

This procedure shall be applied to medical device projects involving computational modeling to evaluate a device or component's technical performance, safety and/or effectiveness.

3.0 DEFINITIONS & ACRONYMS

3.1 Definitions

Context of Use:	A statement that defines the specific role and scope of the computational model used to address the question of interest.
Credibility:	The trust, established through the collection of evidence, in the predictive capability of a computational model for a context of use.
Quantity of Interest:	The output from a computational model that the attributions describe.
Validation:	The process of determining the degree to which a model or simulation is an accurate representation of the real world.
Verification:	The process of determining that a computational model accurately represents the underlying mathematical model and its solution from the perspective of the intended uses of modeling and simulation.

3.2 Acronyms

CM&S	Computational Modeling and Simulation
COU	Context of Use
MOTS	Modified Off-the-Shelf

NCV	Numerical Code Verification
OTS	Off-The-Shelf
PM	Project Manager
QOI	Quantities of Interest
SES	Stress Engineering Services, Inc.
SME	Subject Matter Expert
SQA	Software Quality Assurance
UQ	Uncertainty Qualification
V&V	Verification and Validation

4.0 REFERENCES

ASME V&V 40-2018, *Assessing Credibility of Computational Modeling Through Verification and Validation; Application to Medical Devices*

U.S. Department of Heath and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (2021), *Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions, Draft Guidance for Industry and Food and Drug Administration Staff*

L1-QMS-PR-09, *Deliverables*

L2-CIN-PR-08, *Test and Measurement*

L3-CIN-GD-13, *Good Documentation Practices*

5.0 RESPONSIBILITY

The Project Manager (PM) has overall responsibility for ensuring the requirements of this procedure are implemented and documented.

6.0 REQUIREMENTS

An overview of the V&V process is presented below in Figure 1. This process shall be used to establish risk-informed credibility, demonstrate relevance of credible activities for the intended use, and produce evidence with an acceptable level of confidence within the model's context of use (COU).

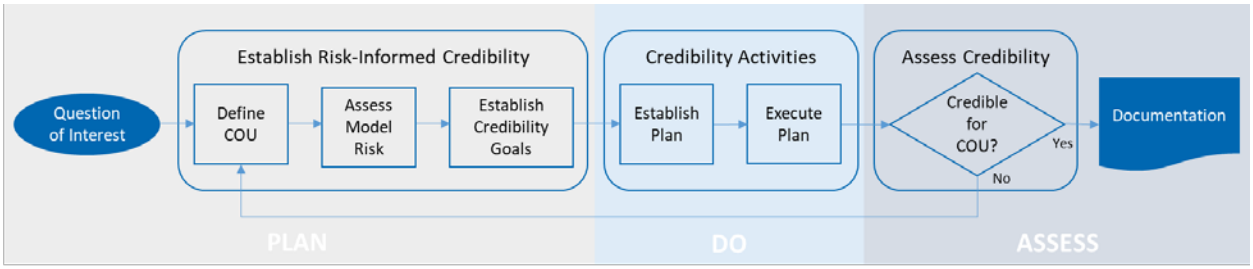

Figure 1. Process Overview

6.1 Step 1: State Question of Interest

The first step is to identify the question of interest. This should describe the specific question, decision or concern that is being addressed.

Example: Can the device meet its functional requirements if its dimensions are reduced by 10%?

6.2 Step 2: State Context of Use

The COU defines the specific scope of the computational model used to address the question of interest. The COU should include:

a) Detailed statement of what will be modelled; and

b) How the outputs from the model will be used to answer or inform the question of interest.

Example: A computational model is used to determine and assess the strength when device dimensions are reduced by 10%. The model will determine if adequate strength is maintained and if the device can function as intended, without harming the patient. The outputs of the model will indicate the stresses in the device for several usage cases. These stresses will be compared against material data and results of tensile tests.

6.3 Step 3: Assess Model Risk

The model risk must be assessed by evaluating the possibility that the use of the computational model leads to a decision that results in patient harm and/or other undesirable impacts. The model

risk is a combination of the influence of the computational model (model influence) and the consequence of an adverse outcome resulting from an incorrect decision (decision consequence).

Influence and consequence shall be individually assessed per the gradation levels defined in Table 1 and Table 2. The model risk is then assessed using a 5-level risk schema defined in Table 3. This risk assessment will be used to define the goals for the model credibility factors.

The model risk assessment will require inputs from all stakeholders and will be reviewed with the client prior to the execution of the V&V activities.

Table 1. Model Influence Gradation Levels

Gradation Level	Description
1	Model outputs provide **little or no impact** on the decision making
2	Model outputs provide **minor** impact on the decision making
3	Model outputs provide **major** impact on the decision making
4	Model outputs provide **critical** impact on the decision making
5	Model outputs provide **sole** impact on the decision making

Table 2. Decision Consequence Gradation Levels

Gradation Level	Description
1	Incorrect decision would **not adversely** affect or nuisance the patient, or have a **negligible** impact on other project, process or other quality decisions
2	Incorrect decision would **not adversely** affect or nuisance the patient, or could have a **minor** impact on other project, process or quality decisions
3	Incorrect decision would **adversely** affect the patient with a **non-permanent** consequence, or **significant** impact to other project, process or quality decisions
4	Incorrect decision would **adversely** affect the patient with a **permanent** consequence, or **serious** impact to other project, process or quality decision
5	Incorrect decision would **adversely** affect the patient with potentially **terminal** consequence, or **critical** impact to other project, process or quality decision

Table 3. Model Risk Assessment

Model Influence Level						
	5	3	3	4	4	5
	4	3	3	3	4	4
	3	2	3	3	3	4
	2	2	2	3	3	3
	1	1	2	2	3	3
		1	2	3	4	5
		Decision Consequence Level				

6.4 Model Credibility

Model credibility refers to the trust in the predictive capability of a computational model for the COU. To establish trust, V&V activities must be completed, with records maintained, and then a demonstration of the applicability of the evidence to support the use of the models for the COU. Activities must be commensurate with the model risk. Credibility factors are listed in Table 4, Table 5 and Table 6.

Table 4. Verification Credibility Factors

Code Verification	Calculation Verification
• Software Quality Assurance • Numerical Code Verification	• Discretization Error • Numerical Solver Error • Use Error

Table 5. Validation Credibility Factors

Computation Model	Comparator	Assessment
• Model Form • Model Inputs	• Test Samples • Test Conditions	• Equivalency of Input Parameters • Output Comparison

Table 6. Applicability Credibility Factors

Applicability
• Relevance of the Quantities of Interest • Relevance of the Validation Activities to the COU

6.5 Verification

Model verification is the process to ensure the mathematical model is implemented correctly and accurately solved for the COU. The verification process is composed of two activities: code verification and calculation verification.

6.5.1 Code Verification

The goals of code verification are to identify and remove errors in the source code and numerical algorithms of the computational software. Code verification activities include software quality assurance and numerical code verification (NCV).

6.5.1.1 Software Quality Assurance

Software quality assurance (SQA) is a process to ensure the code is functioning correctly and produces repeatable results on specified computer hardware and in a specified software environment. The following gradation rigor has been established for SQA.

The SQA credibility goal shall be based on the model risk, with the rationale documented.

Table 7. Software Quality Assurance Credibility Goal

Model Risk	Credibility Goal
1	No SQA is documented for Off-the-Shelf (OTS), modified Off-the-Shelf (MOTS), or user-developed software
2	Defaults to the same level of rigor as in model risk 3
3	Internal SQA procedures are followed and documented for OTS, MOTS or user-developed software, or OTS certified by established quality requirements (i.e. ISO 9001); user documents that the software is functioning as expected on their system
4	Defaults to the same level of rigor as in model risk 5
5	Internal SQA procedures are specified and documented, or OTS is certified through a recognized quality system (i.e. ISO 9001); documentation provides evidence of adequate software performance and known issues per software version (i.e. release notes or reported bugs); potential problems are identified and mitigated

6.5.1.2 Numerical Code Verification

NCV is the process to demonstrate correct implementation and functioning of the numerical code/algorithm, which is typically accomplished by comparing close-form benchmark solutions or methods of manufactured solutions.

The NCV goal shall be based on the model risk, with the rationale documented.

Table 8. Numerical Code Verification Credibility Goal

Model Risk	Credibility Goal
1	NVC is not performed
2	Defaults to the same rigor as in model risk 3
3	The numerical solution for a relevant COU (not necessarily the same COU) is compared to a benchmark solution from another verified/OTS code
4	Numerical solution is compared to a closed-form solution or other analytical or empirical benchmark
5	Grid convergence demonstrates that the numerical solution metric asymptotically approached the exact solution for a relevant COU and discretization error is quantified, or the other of accuracy is quantified and compared to the theoretical order of accuracy

6.5.2 Calculation Verification

The calculation verification is used to estimate the numerical error in the quantities of interest (QOIs) due to spatial and temporal discretization of the model. This process involves the estimation of discretization error, numerical solver error and identification of use error.

6.5.2.1 Discretization Error

Discretization error refers to the error associated with solving the computational problem at a finite number of spatial and/or temporal grid points.

The discretization error credibility goal shall be selected, with the rationale documented.

Table 9. Discretization Error Credibility Goal

Model Risk	Credibility Goal
1	No grid or time-step convergence analysis is performed
2	Defaults to the same rigor as in model risk 3
3	Applicable grid and/or time-step convergence analyses are performed and shown to be stable, but discretization error is not estimated
4	Defaults to the same level of rigor as in model risk 5
5	Problem-specific (i.e., within COU) grid and/or time-step convergence analyses are performed, shown to be stable, and discretization error is estimated

6.5.2.2 Numerical Solver Error

Numerical solver error refers to the error originating from the numerical solution based on the solver parameters that were selected, e.g., convergence tolerance(s).

The numerical solver error credibility goal shall be selected, based on model risk, with rationale documented.

Table 10. Numerical Solver Error Credibility Goal

Model Risk	Credibility Goal
1	No solver parameter sensitivity is performed with no justification provided for choosing a specific convergence criterion
2	Defaults to the same rigor as in model risk 3
3	No solver parameter sensitivity is performed; solver parameters are established based on values from a previously verified computational model or compared to analytical data
4	Defaults to the same rigor as in model risk 5
5	Problem-specific (i.e., within COU) sensitivity study is performed on solver parameters or confirms changes due to solver parameters are negligible relative to the model accuracy goal.

6.5.2.3 Identification of Use Error

The identification of use error refers to errors accrued in the simulation results by the practitioner (i.e., typographical errors).

The identification of use error credibility goal shall be selected, with the rationale documented.

Table 11. Identification of Use Error Credibility Goal

Model Risk	Credibility Goal
1	Key inputs and outputs are verified in an internal peer review and documented in a checking log
2	Key inputs and outputs are verified in an internal peer review and documented in a checking log
3	All Inputs and outputs are verified in an internal peer review and documented
4	All Inputs and outputs are verified in an internal peer review by at least one subject matter expert (SME) and documented
5	All inputs and outputs are verified and documented in an internal peer review by at least two (2) SMEs

6.6 Validation

Model validation is the process of assessing the degree to which the computational model is an appropriate representation of the reality of interest and demonstrates the correctness of the underlying model assumptions and the degree to which sensitivities and uncertainties of the computational model and the associated comparator(s) are understood.

6.6.1 Computational Model

The two credibility factors for the computational model are model form and model inputs, which encompass four components of a computational model:

a) *Governing equations* are the mathematical descriptions of the phenomena being modelled.

b) *System configuration* could be the geometry of the device, the computational domain, the structure of a physiological control system or the in vitro test apparatus that is modelled.

c) *System properties* are the biological, chemical and physical properties used in the computational model.

d) *System conditions* are the constraints that are imposed on the system, such as boundary conditions, loading conditions and initial conditions.

6.6.1.1 Model Form

Model form refers to both the conceptual and mathematical formulation of the computational model and is established or selected based on assumptions that will enable the computational model to achieve the desired predictions within the COU.

The model form credibility goal shall be selected, with the rationale documented.

Table 12. Model Form Credibility Goal

Model Risk	Credibility Goal
1	Influence of model form assumptions is not explored, i.e., not investigated through documented efforts
2	Defaults to the same level of rigor as in model risk 3
3	Influence of key model form assumptions is identified for some of its components (i.e., Governing Equations, System Configuration, System Properties, System Conditions), and their sensitivities are qualitatively explored
4	Influence of key model form assumptions is identified for some of its components (i.e., Governing Equations, System Configuration, System Properties, System Conditions), and their sensitivities are quantitively explored
5	Comprehensive evaluation of mode form assumptions is conducted and applied to the model results as part of the quantification of uncertainties

6.6.1.2 Model Inputs

Model inputs refer to the values for parameters used in the governing equations, system configuration, system properties and system conditions.

The assessment of model input parameters is subdivided into the quantification of sensitivities and quantification of uncertainties.

6.6.1.2.1 Quantification of Sensitivities

Quantification of sensitivities examines the degree to which the computational model outputs are sensitive to the model inputs.

The quantification of sensitivities credibility goal shall be selected, with the rationale documented.

Table 13. Quantification of Sensitivities Credibility Goal

Model Risk	Credibility Goal
1	Influence of model inputs is not explored, i.e., not investigated through documented efforts
2	Defaults to the same level of rigor as in model risk 3
3	Influence of expected key model inputs are quantitively explored
4	Influence of expected key model inputs is explored and applied to the model, including quantification of central tendencies uncertainty; central tendency, e.g., mean uncertainty or other valid distribution statistics, is determined for the uncertainty distribution, although the distribution is not fully characterized
5	Comprehensive evaluation of model inputs is conducted and applied to the model results as part of the uncertainty quantification with defined target goals at the planning stage; uncertainty distribution is characterized

6.6.1.2.2 Quantification of Uncertainties

Quantification of uncertainties examines the degree to which known or assumed uncertainties in the model inputs are propagated to uncertainties in the simulation results.

The quantification of uncertainties credibility goal shall be selected, with the rationale documented.

Table 14. Quantification of Uncertainties Credibility Goal

Model Risk	Credibility Goal
1	Influence of model inputs is not explored (i.e., investigated through documented efforts)
2	Defaults to the same level of rigor as in model risk 3
3	Influence of expected key model inputs are quantitatively explored
4	Influence of expected key model inputs is explored and applied to the model results as part of an uncertainty quantification (UQ); mean uncertainty, or other valid distribution statistic, is determined for the uncertainty distribution, although the distribution is not fully characterized
5	Comprehensive evaluation of model inputs is conducted and applied to the model results as part of an UQ; the UQ target goal is defined during the planning stage; uncertainty distribution is characterized

6.6.2 Comparator

Comparators provide the data against which simulation results are evaluated, which is often physical evidence.

The two credibility factors for the comparator are the test samples (e.g., the medical device) and the test conditions (e.g., physiologic loading). These factors are subdivided into the following components:

a) Quantity

b) Range of characteristics

c) Measurements

d) Measurement uncertainty

6.6.2.1 Quantity of Test Samples

Quantity of test samples examines the number of samples used in the comparator study. Increased credibility is generally achieved with a larger number of samples.

The quantity of test samples credibility goal shall be selected, with the rationale documented.

Table 15. Quantity of Test Samples Credibility Goal

Model Risk	Credibility Goal
1	No samples are used
2	A single sample is used
3	Defaults to the same level of rigor as in model risk 4
4	Multiple samples are used; the confidence interval for mean or other statistical central tendency comparison parameter is calculated
5	Multiple samples are used; the confidence interval for mean and standard deviation or other statistical central tendency and dispersion comparison parameters are calculated

6.6.2.2 Range of Characteristics of Test Samples

Range of characteristics of test samples examine the range of each test sample characteristic of interest included in the comparator study. Range characteristics include key sample features, e.g., critical-to-quality attributes. Increased credibility is generally achieved with a broader range examination of test sample characteristics.

The range of characteristics of test samples credibility goal shall be selected, with the rationale documented.

Table 16. Range of Characteristics of Test Samples Credibility Goal

Model Risk	Credibility Goal
1	No samples are examined
2	One sample with a single set of characteristics is examined
3	More than one sample with a single set of characteristics are examined
4	Test conditions representing a range of conditions near nominal are examined
5	Test conditions representing the values within the range are examined

6.6.2.3 Measurement of Test Samples

Measurement of test samples examines the degree of coverage with which the measurement data characterizes each test sample. This component includes characterization for comparator inputs (e.g., test sample dimensions, material properties) as well as characterization of comparator outputs (e.g., test sample yield strength).

The measurement of test samples credibility goal shall be selected, with the rationale documented.

Table 17. Measurement of Test Samples

Model Risk	Credibility Goal
1	Test samples are not measured or characterized
2	Defaults to the same level of rigor as in model risk 3
3	One or more key characteristics of the test samples are measured
4	Defaults to the same level of rigor as in model risk 5
5	All key characteristics of the test samples are measured

6.6.2.4 Uncertainty of Test Sample Measurements

Uncertainty of test sample measurements examines the analysis of uncertainty associated with the tools and methods used to obtain the measurements characterizing the samples.

Table 18. Uncertainty of Test Sample Measurements

Model Risk	Credibility Goal
1	Measurement uncertainty is not addressed; samples are not characterized or are characterized with gross observations
2	Defaults to the same level of rigor as in model risk 3
3	Uncertainty is addressed leveraging instrument supplier's or other data not generated in a designed experiment for uncertainty analysis
4	Uncertainty analysis incorporated instrument accuracy and repeatability (i.e., statistical treatment of repeated measurements)
5	Analysis incorporates a comprehensive uncertainty quantification, including instrument accuracy, repeatability, and other conditions affecting the measurements; uncertainty analysis meets a predefined target goal defined during the planning stage

6.6.3 Test Conditions

6.6.3.1 Quantity of Test Conditions

Quantity of test conditions examines the number of conditions imposed and characterized in the comparator study. Increased credibility is generally achieved with a larger number of test conditions.

The quantity of test conditions credibility goal shall be selected, with the rationale documented.

Table 19. Quantity of Test Conditions Credibility Goal

Model Risk	Credibility Goal
1	A single test condition is examined
2	Defaults to the same level of rigor as in model risk 3
3	Multiple test conditions are examined
4	Defaults to the same level of rigor as in model risk 5
5	All relevant test conditions are examined

6.6.3.2 Range of Test Conditions

The range of test conditions examines the range to conditions in the comparator study. Increased credibility is generally achieved by examining a broader range of test conditions.

The range of test conditions credibility goal shall be selected, with the rationale documented.

Table 20. Range of Test Conditions Credibility Goal

Model Risk	Credibility Goal
1	A single test condition is examined
2	Multiple ad hoc test conditions are examined
3	Test conditions representing a range of conditions near nominal are examined
4	Defaults to the same level of rigor as in model risk 5
5	Test conditions representing the values within the entire range are examined

6.6.3.3 Measurement of Test Conditions

Measurement of test conditions examines the degree of coverage with which the measurement data characterizes each test condition. Increased credibility is generally achieved by examining a broader, more complete set of test conditions.

The measurement of test conditions credibility goal shall be selected, with the rationale documented.

Table 21. Measurement of Test Conditions Credibility Goal

Model Risk	Credibility Goal
1	No test conditions are measured
2	Test conditions are qualitatively measured or characterized
3	One or more key characteristics of the test conditions are measured
4	Defaults to the same level of rigor as in model risk 5
5	All key characteristics of the test conditions are measured

6.6.3.4 Uncertainty of Test Conditions Measurements

Uncertainty of test condition measurements examines the analysis of uncertainty associated with the tools and methods used in measurements and characterize the test conditions. Credibility increases with decreased test condition measurement uncertainty.

The uncertainty of test conditions measurements credibility goal shall be selected, with the rationale documented.

Table 22. Uncertainty of Test Conditions Measurements Credibility Goal

Model Risk	Credibility Goal
1	Test conditions are not characterized or are characterized by gross observations; measurement uncertainty is not addressed
2	Defaults to the same level of rigor as in model risk 3
3	Uncertainty analysis incorporated instrument accuracy only
4	Uncertainty analysis incorporated instrument accuracy and repeatability (i.e., statistical treatment of repeated measurements)
5	Uncertainty analysis incorporated a comprehensive uncertainty quantification, which included instrument accuracy, repeatability, and other conditions affecting the measurements; uncertainty analysis meets a predefined target goal defined during the planning stage

6.6.4 Assessment

An assessment of the accuracy of the simulation output can be performed after the outputs from the V&V activities are obtained and compared. The credibility goals associated with this assessment are the equivalency of the input parameters and the rigor of the output comparison.

6.6.4.1 Equivalency of Input Parameters

Equivalency of input parameters evaluates the degree of equivalency between type and range of input parameters of the computational model and those of the comparator. Increased credibility is generally achieved with a larger degree of equivalency.

The equivalency of input parameters credibility goal shall be selected, with the rationale documented.

Table 23. Equivalency of Input Parameters Credibility Goal

Model Risk	Credibility Goal
1	The types of inputs are dissimilar or unknown
2	Defaults to the same level of rigor as in model risk 3
3	The types of all inputs are similar, but the ranges are not equivalent
4	Defaults to the same level of rigor as in model risk 5
5	The types and ranges of all inputs are equivalent

6.6.4.2 Quantity of Outputs

Quantity of outputs examines the number of outputs or quantity of interest (QOI) being compared. Increased credibility is generally achieved with the examination of a larger number of outputs or QOI compared.

The quantity of outputs credibility goal shall be selected, with the rationale documented.

Table 24. Quantity of Outputs Credibility Goal

Model Risk	Credibility Goal
1	A single output is compared
2	Defaults to the same level of rigor as in model risk 3
3	Multiple outputs are compared
4	Defaults to the same level of rigor as in model risk 5
5	Multiple outputs are compared

6.6.4.3 Equivalency of Output Parameter

Equivalency of output Parameter examines the type of output or QOI being compared. It does not consider the values of the outputs. Increased credibility is generally achieved with the increased similarity of types of outputs.

The equivalency of output parameter credibility goal shall be selected, with the rationale documented.

Table 25. Equivalency of Output Parameter

Model Risk	Credibility Goal
1	Types of outputs are dissimilar
2	Defaults to the same level of rigor as in model risk 3
3	Types of outputs are related
4	Defaults to the same level of rigor as in model risk 5
5	Types of outputs are equivalent

6.6.4.4 Rigor of Output Comparison

Rigor of output comparison refers to the method used to compare the QOIs from the computational model to the comparator. Increased credibility is generally achieved with increased statistical rigor of the comparison method.

The rigor of output comparison credibility goal shall be selected, with the rationale documented.

Table 26. Rigor of Output Comparison Credibility Goal

Model Risk	Credibility Goal
1	Visual comparison is performed
2	Comparison is performed by determining the arithmetic difference between computational results and experimental results
3	Comparison is performed by calculating the confidence interval or other statistical comparison parameter without a predefined target goal
4	Uncertainty in the output of the computational model or the comparator is used in the output comparison
5	Uncertainties in the output of the computational model and the comparator are used in the output comparison; the statistical comparison criterion's target goal is defined during the planning stage and supports high precision model output

6.6.4.5 Agreement of Output Comparison

Agreement of output comparison examines the qualitative or quantitative agreement between QOIs from the computational model and those from the comparator. Increased credibility is generally achieved with closer agreement for comparisons.

The agreement of output comparison credibility goal shall be selected, with the rationale documented.

Table 27. Agreement of Output Comparison Credibility Goal

Model Risk	Credibility Goal
1	The level of agreement of the output comparison is marginal for key comparisons
2	Defaults to the same level of rigor as in model risk 3
3	The level of agreement of the output comparison is satisfactory for key comparisons, but not all comparisons
4	Defaults to the same level of rigor as in model risk 3
5	The level of agreement of the output comparison is satisfactory for all comparisons

6.7 Applicability of the Validation Activities to the COU

6.7.1.1 Relevance of the QOIs

Relevance of QOIs compares the QOIs from the validation activities to the QOIs for the COU. Credibility increases with increasing overlap among the validations and COU QOIs.

The relevance of QOIs credibility goal shall be selected, with the rationale documented.

Table 28. Relevance of the QOIs Credibility Goal

Model Risk	Credibility Goal
1	The QOIs from the validation activities are related, though not equivalent, to those for the COU
2	Defaults to the same level of rigor as in model risk 3
3	A subset of the QOIs from the validation activities is equivalent to those for the COU
4	Defaults to the same level of rigor as in model risk 5
5	All QOIs from the validation activities are equivalent to those for the COU

6.7.2 Relevance of the Validation Activities to the COU

Relevance of the validation activities summarizes the relative proximity of the COU to validation points. Credibility is proportional to their overlap.

Table 29. Relevance of the Validation Activities Credibility Goal

Model Risk	Credibility Goal
1	The is no overlap between the ranges of the validation points and the COU
2	Defaults to the same level of rigor as in model risk 3
3	There is a partial overlap between the ranges of the validation points and the COU
4	The COU encompassed some of the validation points
5	The COU encompasses all validation points, and the validation points spanned the entire COU space

6.8 Develop and Approve V&V Credibility Goals Plan

The purpose of the plan is to define the appropriate activities and acceptable results for each credibility factor that establishes the model credibility commensurate with the model risk. The plan will be developed by SES based on inputs from all stakeholders from the client side. The plan does not necessarily define the protocols for executing the activities. The development of a plan will help facilitate the communication among all stakeholders. Upon completion, the plan will be reviewed by and approved by all stakeholders, indicating that the overall credibility will be sufficient to use the computational model for the COU and the associated model risk.

The plan for assessing the credibility of the computational model may contain the following information:

a) Question of interest

b) COU of the computational model

c) Description of the computational model

d) Model risk assessment

e) Purpose of the credibility activities

f) Credibility factors and corresponding credibility goals

g) Activities and rationale for each credibility factor

6.9 Credibility Assessment

The credibility assessment is a review of completed V&V activities and outcomes that establish model credibility commensurate with the model risk.

6.10 Documentation

Detailed records shall be maintained. Pursuant to L1-QMS-PR-09, *Deliverables*, records shall be maintained to document checking of the models.

Any testing completed in support of this procedure shall be in accordance with L2-CIN-PR-08, *Test and Measurement*, with the adequate details included in the test records. In addition, L3-CIN-GD-13, *Good Documentation Practices*, shall be followed.

Upon completion of the models and any applicable testing, the results shall be documented in a written report. The report shall contain the following:

- Background
- COU of the computational model
- Computation model details
- Model risks
- Credibility activities, results and computational model credibility assessment
- Conclusions and next steps

7.0 REVISION HISTORY

Document Control					
Rev	**Date**	**Description**	**Originator**	**Checker**	**Reviewer**
0	17-Aug-2022	Initial release	NBillade	AStuckenberg	MBurchnall