

INTERAGENCY AGREEMENT		1 IAA NO NRC-HQ-20-16-T-0C13		PAGE OF 1 3	
7 ORDER NO		3 REQUISITION NO NRR-16-0223		4 SOLICITATION NO	
5 EFFECTIVE DATE 08/26/2016		6 AWARD DATE 08/26/2016		7 PERIOD OF PERFORMANCE 08/29/2016 TO 08/28/2018	
8 SERVICING AGENCY BROOKHAVEN NATIONAL LABORATORY ALC: DUNS: 627579460 +4: BROOKHAVEN SITE OFFICE PO BOX 5000 BLDG 464 UPTON NY 11973-5000 POC Kim Nekulak TELEPHONE NO 631-344-7439			9 DELIVER TO LESLIE PERKINS US NUCLEAR REGULATORY COMMISSION ONE WHITE FLINT NORTH BUILDING 11555 ROCKVILLE PIKE MAIL STOP O-12D20 ROCKVILLE MD 20852		
10 REQUESTING AGENCY ACQUISITION MANAGEMENT DIVISION ALC: 31000001 DUNS: 040535809 +4: US NUCLEAR REGULATORY COMMISSION ONE WHITE FLINT NORTH 11545 ROCKVILLE PIKE MAIL STOP T-5E3 ROCKVILLE MD 20852-2738 POC Carolyn A. Cooper TELEPHONE NO 301-415-6734			11 INVOICE OFFICE US NUCLEAR REGULATORY COMMISSION ONE WHITE FLINT NORTH 11555 ROCKVILLE PIKE MAILSTOP O3-E17A ROCKVILLE MD 20852-2738		
12 ISSUING OFFICE US NRC - HQ ACQUISITION MANAGEMENT DIVISION MAIL STOP TWEN-5E03 WASHINGTON DC 20555-0001			13 LEGISLATIVE AUTHORITY Energy Reorganization Act of 1974		
			14 PROJECT ID		
			15 PROJECT TITLE AURORA-B LOCA EVALUATION		
16 ACCOUNTING DATA 2016-X020J-FREEBASED-20-20DC06-11-4-151-1065-251D					
17 ITEM NO	18 SUPPLIER/SERVICES	19 QUANTITY	20 UNIT	21 UNIT PRICE	22 AMOUNT
	NRC-HQ-20-16-T-0013 The NRC and the DOE Laboratory (BNL) hereby enter into this Agreement for the project entitled, "Technical Assistance in Support of the Review of AREVA Topical Report, ANP-10332P, Rev 0, "AURORA-B: An Evaluation Model for Boiling Water Reactors; Application to Loss of Coolant Accident Scenarios." NRC COR: Leslie Perkins (301)415-2375 ALT COR: Brian Harris (301)415-2277 Continued ...				
23 PAYMENT PROVISIONS			24 TOTAL AMOUNT \$177,000.00		
25a SIGNATURE OF GOVERNMENT REPRESENTATIVE (SERVICING) <i>Kim Nekulak</i>		26a SIGNATURE OF GOVERNMENT REPRESENTATIVE (REQUESTING) <i>Carolyn A. Cooper</i>			
25b NAME AND TITLE Kim Nekulak, Contracting Officer		25c DATE SEP 8 2016		26b CONTRACTING OFFICER CAROLYN A. COOPER	
				26c DATE 8/26/2016	

BNL PI: Lap-Yan Cheng (631)344-2336

The period of performance of this agreement shall commence on August 29, 2016 and shall end on August 28, 2018. Notwithstanding the agreement effective dates and period of performance start dates stated in the agreement, the effective date of the agreement and start date of the period of performance are the last date of signature by the parties.

CONSIDERATION AND OBLIGATIONS:

(a) Authorized Cost Ceiling Amount: \$335,614.00
(b) The amount presently obligated with respect to this DOE Agreement is \$177,000.00. When and if the amount(s) paid and payable to the DOE Laboratory equals the obligated amount, the DOE Laboratory shall not be obligated to continue performance of the work unless and until the NRC Contracting Officer increases the amount obligated with respect to this DOE Agreement. Any work undertaken by the DOE Laboratory in excess of the obligated amount specified above is done so at the DOE Laboratory's sole risk.

The following documents are hereby made part of this Agreement:

- Attachment No. 1: Statement of Work
- Attachment No. 2: DOE Standard Terms and Conditions

The work hereunder is Fee-Recoverable.
The TAC Number is MF3829
The Docket Number is PROJ0728

Master IAA: NRCHQ2514DC002

00001

New Task Order
Line Item Ceiling \$335,614.00
Incrementally Funded Amount: \$177,000.00

335,614.00

This agreement is entered into pursuant to the authority of the Energy Reorganization Act of 1974, as amended (42 U.S.C 5801 et seq.). This work will be performed in accordance with the NRC/DOE Memorandum of Understanding dated
Continued ...

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NRC-HQ-20-16-T-0013

ORDER NO

PAGE

OF

3

3

November 24, 1998. To the best of our knowledge, the work requested will not place the DOE and its contractor in direct competition with the domestic private sector.

The total amount of award: \$335,614.00. The obligation for this award is shown in box 24.

STATEMENT OF WORK (SOW)

NRC Agreement Number	NRC Agreement Modification Number	NRC Task Order Number (If Applicable)	NRC Task Order Modification Number (If Applicable)
NRC-HQ-25-14-D-0002		NRC-HQ-20-16-T-0013	
Project Title Technical Assistance in Support of Review of AREVA Topical Report ANP-10332P, "AURORA-B: An Evaluation Model for Boiling Water Reactors; Application to Loss of Coolant Accident Scenarios"			
Job Code Number	B&R Number	Servicing Agency BNL	
NRC Requisitioning Office NRR		Period of Performance Two years from date of award	
NRC Form 187, Contract Security and Classification Requirements <input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable		<input checked="" type="checkbox"/> Involves Proprietary Information <input type="checkbox"/> Involves Sensitive Unclassified	
<input type="checkbox"/> Non Fee-Recoverable		<input checked="" type="checkbox"/> Fee-Recoverable (If checked, complete all applicable sections below)	
Docket Number (If Fee-Recoverable/Applicable) PROJ0728		Inspection Report Number (If Fee Recoverable/Applicable)	
Technical Assignment Control Number (If Fee-Recoverable/Applicable) MF3829		Technical Assignment Control Number Description (If Fee-Recoverable/Applicable) AREVA NP INC. - ANP-10332P. REVISION 0, "AURORA-B: AN EVALUATION MODEL FOR WRS; APPLICATION TO LOSS OF COOLANT ACCIDENT	

DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

1.0 BACKGROUND

AREVA topical report ANP-10332P presents a proprietary evaluation model for performing licensing-basis analysis for boiling-water reactors (BWRs) in response to a postulated loss-of-coolant accident (LOCA) event. Topical report ANP-10332P describes a deterministic LOCA evaluation model that is intended to satisfy the required and acceptable emergency core cooling system (ECCS) evaluation model features specified in Appendix K to 10 CFR 50. If deemed acceptable, AREVA intends to use this method to perform LOCA analysis for BWRs to ensure satisfaction of the criteria of 10 CFR 50.46 (namely peak cladding temperature, maximum local oxidation, and core-wide oxidation).

The methodology described in ANP-10332P is based on a multi-physics code system known as AURORA-B. For the LOCA evaluation model, the AURORA-B code system relies upon two main components, S-RELAP5 (thermal-hydraulic system code) and RODEX4 (transient fuel thermal-mechanical behavior code). Up to the present time, AURORA-B and/or its constituent component codes have been or are in the process of being reviewed by the NRC staff on a number of other applications, including:

- EMF-2328PA, PWR Small Break LOCA Evaluation Model
- EMF-2103PA, Realistic Large Break Loss-of-Coolant Accident Methodology for Pressurized Water Reactors
- EMF-2310PA, SRP Chapter 15 Non-LOCA Methodology for Pressurized Water Reactors
- BAW-10247PA, Realistic Thermal-Mechanical Fuel Rod Methodology for Boiling Water Reactors
- ANP-10300P, AURORA-B: An Evaluation Model for Boiling Water Reactors; Application to Transient and Accident Scenarios (currently under review)
- ANP-10333P, AURORA-B: An Evaluation Model for Boiling Water Reactors; Application to Control Rod Drop Accident (currently under review)

The NRC staff intends to maintain overall responsibility for the review of the topical report, whereas BNL shall be requested to provide focused technical assistance concerning the validation of the AURORA-B code system against test data that is applicable to the BWR LOCA event, including both separate effects and integral comparisons. This information is contained largely in Chapter 7 of the topical report, which comprises the bulk of the topical report.

In light of the above discussion, BNL's review should focus on the following:

- The adequacy of the validation of specific models and correlations of highest importance to the BWR LOCA event,
- The adequacy of the validation of specific models and correlations that have been added or modified relative to implementations previously reviewed by the NRC staff (e.g., to support application to the BWR LOCA event, to support coupling of the constituent component codes together, or otherwise),
- Novel impacts from applying existing models and correlations to the BWR LOCA event, which may, for example, result in the use of existing models and correlations outside of ranges considered in the validation process for previous applications,
- The degree of adherence of specific models and correlations to the required and acceptable features of ECCS evaluation models set forth in 10 CFR 50, Appendix K;
- Consideration of whether the validation database used by AREVA is applicable and sufficient to support application of the AURORA-B code system to the analysis of the BWR LOCA event, and
- Review of additional code models and correlations, if justified in light of present knowledge and recent developments.

Upon completion of our acceptance review for ANP-10332P, the NRC staff will provide additional guidance regarding the specific models and correlations to which BNL should pay special attention during the review.

2.0 OBJECTIVE

The objective of this task order is to obtain technical assistance in support of the NRC staff's determination concerning whether the subject topical report (ANP-10332P) is technically accurate and meets applicable regulatory requirements. The NRC technical staff will participate in this review and retain overall project leadership. Technical assistance from BNL is being requested in the specific area of ensuring adequate validation of the models and correlations in the AURORA-B code system for performing licensing-basis BWR LOCA analysis in accordance with the requirements of Appendix K to 10 CFR 50. The information to be reviewed by BNL is contained largely in Chapter 7 of ANP-10332P.

3.0 SCOPE OF WORK/TASKS

The NRC will furnish a copy of topical report ANP-10332P and other supporting documentation in our possession. Beyond this, BNL shall provide all resources necessary to accomplish the tasks and deliverables described in this statement of work (SOW). BNL shall provide technical review resources for evaluating the validation of the models and correlations used in the AURORA-B code system, as described primarily in Chapter 7 of AREVA's topical report ANP-10332P.

The services include supporting a kick-off meeting, reviewing relevant portions of ANP-10332P, traveling to NRC Headquarters or vendor's office to perform one or more regulatory audits (if necessary), participating in periodic telephone conference calls with the vendor, identifying issues and draft requests for additional information (RAIs), evaluating vendor's RAI responses, providing a technical evaluation report, and supporting the NRC staff during the associated Advisory Committee on Reactor Safeguards (ACRS) meeting (if applicable).

Task 1: Kick-off Meeting

The serving agency shall participate in a telephone conference call orientation/kick-off meeting with the NRC staff to discuss the scope of the work, expectations and contract management.

BNL shall provide a technical letter report. (See Section 8.2 for Technical Letter Report requirements).

Task 2: Supporting Regulatory Audit of Topical Report

The staff from BNL shall prepare for and travel to NRC headquarters or the vendor site for a regulatory audit of topical report that focuses on outstanding questions generated by the NRC staff and servicing agency review effort to date (if *deemed necessary by NRG GOR*).

Subtask 2a: One week prior to the audit, BNL shall submit a list of outstanding questions generated from the review of the topical report to date to support discussion with AREVA during the audit.

Subtask 2b: Within two weeks of completion of the audit, BNL shall prepare and submit a trip report via email. (See Section 8.2 for Trip Report requirements)

Task 3: Evaluation of Topical Report

Based upon its review of the validation of the models and correlations of the AURORA-8 code system, as discussed in Chapter 7 of AREVA's topical report ANP-10332P, the serving agency shall provide a draft Technical Evaluation Report (TER) with open items which presents the technical evaluation of the applicant's topical report against the NRC's regulations and guidance. Portions of the topical report which have been found acceptable should be fully documented.

Draft RAIs based upon the remaining open items must be provided to the NRC COR. The draft RAIs should clearly and concisely identify the information being requested, briefly note the regulatory basis for the request, and have a direct connection with an open item. These RAIs are to be emailed to the NRC COR along with the draft TER with open items. (See Section 8.2 for Technical Evaluation Report requirements).

Task 4: Supporting Regulatory Audit of RAI Responses

The staff from BNL shall prepare for and travel to NRC headquarters or the vendor site for a regulatory audit of AREVA RAI responses (which may be in draft form) that focuses on the adequacy of the approach AREVA is using to resolve the outstanding RAI questions (*if deemed necessary by NRG GOR*).

Within two weeks of completion of the audit, BNL shall prepare and submit a trip report via email. (See Section 8.2 for trip report requirements)

Task 5: Review and Evaluation of RAI Responses

BNL shall review and evaluate the RAI responses formally submitted by the vendor to determine whether or not the responses address the concerns identified in the original RAI. BNL shall prepare and submit an updated version of the draft TER provided under Task 3, which includes documentation of the RAI response evaluation. For RAI responses that are unacceptable, formulate follow-up RAI(s).

BNL shall review the vendor's response(s) to the follow-up RAI(s) and submit a revised TER documenting the evaluation. (See Section 8.2 for TER requirements)

Task 6: Prepare Presentation for ACRS Meeting(s)

BNL shall support NRC staff by providing draft slide presentation summarizing key issues of their evaluation pertaining to ANP-10332P to be used as part of the NRC staff presentation to the ACRS (*if deemed necessary by NRG COR*). If requested by NRC COR, BNL must attend the ACRS meeting.

4.0 LIST OF DELIVERABLES

The following is a list of deliverables and the corresponding due dates that are to be delivered by BNL to the COR during performance of the requirements:

Task Number	Deliverable and Acceptance Criteria	Deliverable Format	Due Date
1	Technical Letter Report Acceptance Criteria: Summary of kickoff meeting as detailed in SOW Section 8.2	Microsoft Word	NLT 14 days from completion of kickoff meeting
2a	Technical Letter Report (If Applicable) Acceptance Criteria: Report contains all required information as detailed in SOW Section 8.2	Microsoft Word	NLT 7 days prior to audit
2b	Trip Report (If Applicable) Acceptance Criteria: Report contains all required information as detailed in SOW Section 8.2	Microsoft Word	NLT 14 days from completion of audit
3	Technical Evaluation Report Acceptance Criteria: Report includes required information as detailed in SOW Section 8.2	Microsoft Word	Draft Report – 6 months from date of award Final report - 2 weeks from receipt of comments from the NRC Technical Monitor
4	Trip Report (If Applicable) Acceptance Criteria: Report contains all required information as detailed in SOW Section 8.2	Microsoft Word	NLT 14 days from completion of audit
5	Technical Evaluation Report Acceptance Criteria: Report includes required information as detailed in SOW Section 8.2	Microsoft Word	Draft Report – 2 months from date receipt of AREVA's RAI responses Final report - 2 weeks from receipt of comments from the NRC Technical Monitor
6	ACRS Slide Presentation (If Applicable)	PowerPoint	Draft Slides: Two weeks prior to the ACRS meeting Final Slides: Two days after receipt of NRC comments
All	Per SOW Section 8.1, Monthly Letter Status Reports (MLSRs) Acceptance Criteria: Report contains all required information	Microsoft Word or Adobe PDF	NLT than 20th of the following month

5.0. ESTIMATED LABOR CATEGORIES AND KEY PERSONNEL

5.1 Labor Categories, Requirements and Key Personnel. Personnel working under this agreement/order shall meet the minimum requirements for experience and education, as follows:

Labor Category	Position Minimum Requirements	Key Personnel* (yes or no)
Senior Key Staff	Expertise in the area of thermal-hydraulic system code and fuel thermal-mechanical analysis for the BWR LOCA event. Knowledge of the body of test data available for benchmarking thermal-hydraulic code models and correlations for this event. Past experience either performing or reviewing code validation efforts for the BWR LOCA event.	Yes

5.2 Changes to Senior Key Staff. BNL shall notify the COR and the NRC technical monitor sufficiently early regarding any senior staff changes during the review. BNL shall consult with the COR and the technical monitor about the expertise and experience of the new senior key staff. The NRC reserves the right to terminate or modify the agreement if the agency is not fully satisfied with the new senior staff assigned to the review.

6.0 MEETINGS AND TRAVEL

Telephone conference call/kickoff meeting with servicing agency, the NRC Technical Monitor, and the COR.

The following travel assumptions should be considered in planning the work effort. It is likely that a smaller group than the entire review team will be necessary to accomplish some activities. The actual travel will be determined by the COR after discussion with the laboratory PM (and PTL). At the discretion of the COR, meetings may be conducted via telephone or video conference. It is anticipated that the following travel will be required:

- One 1-person, 4-day trip to vendor's location or NRC Headquarters (Task 2)
- One 1-person, 4-day trip to vendor's location or NRC Headquarters (Task 4)
- One 1-person, 3-day trip to NRC headquarters for ACRS meeting (Task 6)

Servicing agency personnel will be authorized travel expenses consistent with the Federal Travel Regulation (FTR) and the limitation of funds specified for the travel within this agreement/order. All travel requires prior written approval from the COR.

Foreign travel for BNL personnel requires a 60-day lead time for NRC approval. For prior approval of foreign travel, BNL shall submit to the COR an NRC Form 445, "Request for Approval of Official Foreign Travel." NRC Form 445 is available in the MD 11.7 Documents library and on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/forms/>. All foreign travel requires prior written approval from the NRC Executive Director for Operations (EDO).

7.0 REPORTING REQUIREMENTS

BNL is responsible for structuring the deliverables to current agency standards. The current agency standard is Microsoft Office Suite 2010. The current agency Portable Document Format (PDF) standard is Adobe 9 Professional. Deliverables shall be submitted free of spelling and grammatical errors and shall conform to requirements stated in this section.

7.1 Monthly Letter Status Report (MLSR)

BNL shall provide a Monthly Letter Status Report which consists of a technical progress report and financial status report. This report will be used by the NRC to assess the adequacy of the resources utilized by BNL to accomplish the work contained in this SOW and to provide status of BNL progress in achieving tasks and producing deliverables. The report shall include agreement/order summary information, work completed during the specified period, milestone schedule information, problem identification and resolution, travel plans, and staff hour summary.

7.2 Technical Reporting Requirements

1. At the completion of Task 1, submit technical letter report that contains a summary of the meeting, discussions held, and decisions reached.
 - a. One week prior to the audit described in Task 2, submit technical letter report that contains outstanding questions based upon review of topical report to date. The questions included in technical letter report will be used to support audit discussions with AREVA.
 - b. At the completion of Task 2, submit trip report that contains a summary of the audit, including discussions held, outcomes and proposed additional information items that should be requested from vendor to support the review. Include copy of the slides or other visuals used (not necessary if the staff indicates they already have them).
2. At the completion of Task 3, submit technical evaluation report, draft and final as appropriate, that contains input summarizing the review and providing preliminary conclusions. The technical evaluation report should also identify additional information needed to complete the review in the form of draft RAIs. The technical evaluation report and draft RAIs should follow the guidance, format, and content shown in attachments 1 and 2
3. At the completion of Task 4, submit trip report that contains a summary of the audit, including discussions held, outcomes and proposed additional information items that should be requested from vendor to support the review. Include copy of the slides or other visuals used (not necessary if the staff indicates they already have them).

4. At the completion of Task 5, submit technical evaluation report, draft and final as appropriate, that contains revised input, open items, and proposed conditions and limitations. The report should follow the guidance, format, and content shown in Attachment 2.

NOTE: All reports are to be submitted electronically using MS WORD or compatible software program to the Technical Monitor with a copy provided the COR. The transmittal letter and cover page shall contain task order number, title, and NRC cost activity code (CAC).

8.0 CONTRACTING OFFICER'S REPRESENTATIVE

Contracting Officer's Representative

Name: Leslie Perkins
Agency: U.S. Nuclear Regulatory Commission
Office: NRR/DPR/PLPB
Mail Stop: OWFN 12D20
Washington, DC 20555
leslie.perkins@nrc.gov
Phone: (301) 415-2375

Alt. Contracting Officer's Representative

Name: Brian Harris
Agency: U.S. Nuclear Regulatory Commission
Office: NRR/DPR/PGCB
Mail Stop: OWFN 12D20
Washington, DC 20555
brian.harris2@nrc.gov
Phone: (301) 415-2277

Technical Monitor

Name: John Lehning
Agency: U.S. Nuclear Regulatory Commission
Office: NRR/DSS/SNPB
Mail Stop: OWFN 10A 01
Washington, DC 20555
john.lehning@nrc.gov
Phone: (301) 415-1015

9.0 PERIOD OF PERFORMANCE

The period of performance of this task order shall be two years from the effective date of the task order.

10.0 APPLICABLE PUBLICATIONS (CURRENT EDITIONS)

- NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR
- Title 10 Code of Federal Regulations
- Regulatory Guide 1.203, Transient and Accident Analysis Methods

11.0 DATA RIGHTS

The NRC shall have unlimited rights to and ownership of all deliverables provided under this agreement/order, including reports, recommendations, briefings, work plans and all other deliverables. All documents and materials, to include the source codes of any software, produced under this agreement/order are the property of the NRC with all rights and privileges of ownership/copyright belonging exclusively to the NRC. These documents and materials may not be used or sold by BNL without prior written authorization from the CO. All materials supplied to the NRC shall be the sole property of the NRC and may not be used for any other purpose. This right does not abrogate any other Government rights.

12.0 NRC-FURNISHED PROPERTY/MATERIALS

A copy of AREVA Topical Report ANP-10332P, "AURORA-8: An Evaluation Model for Boiling Water Reactors; Application to Loss of Coolant Accident Scenarios," will be made available to BNL. Copies of relevant supporting documentation will be provided, including access to previously approved licensing topical reports that are necessary to perform the review.

NOTE: These documents contain proprietary information and must be safeguarded against unauthorized disclosure. After completion of work, the documents should either be destroyed or returned to NRC. If they are destroyed, please confirm this in an E-mail to the Contracting Officer's Representative(s) with a copy to the Project Officer and include the date and manner in which the documents were destroyed.

Guidance for Preparing Requests for Additional Information (RAIs)

Additional information necessary to resolve open or unresolved items identified during the review of the information associated with the Topical Report needs to be requested in a manner that is unambiguous, has an adequate basis, and is necessary for the safety review. The technical letter report described in Technical Reporting Requirements should provide a list of RAIs using the following guidance:

1. An RAI should include the appropriate basis for requesting the information. The basis should explain why the information is needed, including how it will be used to help make a reasonable assurance finding.
2. Judgmental language should be avoided.
 - a. Questions should not make adequacy determinations.
 - b. Words like "unacceptable," "deficient," and "deviation" should be avoided. Likewise, avoid using phrases like "the staff will require" since it is premature to require anything when asking questions.
3. Questions should be focused, not open-ended.
 - a. The RAI should be in the form of a question or an imperative to provide what is needed to complete the review. When the reviewer needs specific information or the underlying issue may not be apparent, the RAI should clearly identify the information requested and/or the underlying issue.

After the RAIs have been forwarded to the technical monitor, teleconferences and/or public meetings may be held before issuing the RAIs:

- a. These discussions prevent misunderstandings of the intent of the questions.
- b. If a draft RAI is clarified or resolved before issuance, the NRC staff will prepare a documented record of the resolution (i.e., minutes of a public meeting or a teleconference summary).

After the RAIs have been issued, the applicant may request a telephone conference and/or a public meeting:

- a. The teleconferences and/or meetings provide additional clarification of the intent of the RAIs and will help the applicant prepare satisfactory responses.
- b. To ensure that the response appropriately addresses the RAI, the applicant may submit a draft response (which the NRC Project Manager docket in the Agency-Wide Documents Access and Management System (ADAMS)) and may request a follow-up teleconference and/or meeting.

After receiving the applicant's response to the RAI, the technical monitor may hold a teleconference and/or a public meeting. The purpose of discussing a response with the applicant is to better understand the response and/or clarify areas of disagreement. If the resolution of a response relies on information not submitted to the NRC, the applicant should submit the information on the docket. Only docketed information will be taken into consideration when determining the staff's conclusion.

Enclosure 2

Content, Outline, and Format for Technical Evaluation Report**1.0 Introduction**

Summary of Work Performed: Describe the requested action. Outline the methodology used (by the PI) for evaluating the topical report.

2.0 Regulatory Evaluation and Criteria

Describe the regulations and regulatory guidance that the validation process for the models and correlations in the AURORA-B code system is intended to satisfy. Primarily, this would include relevant steps in the evaluation model development and assessment process, as described in Regulatory Guide 1.203, upon which the topical report structure is modeled. Discussion of applicable sections from the Standard Review Plan (e.g., 15.0.2, 15.6.5) that are relevant to evaluation model validation is also appropriate.

3.0 Technical Evaluation

The structure of the technical evaluation section should, insofar as reasonable, mirror the structure of the topical report, which is based on the evaluation model development and assessment process documented in Regulatory Guide 1.203.

3.1 Document your evaluation of the methodology, modeling, and supporting empirical and experimental database used for validation. Include language clearly linking how your assessment of the subject matter is supported (or not supported) by the supporting empirical and experimental database used for validation of the code.

3.2 Document any independent calculations performed in support of assessing the methodology. Provide a direct comparison of your independent results to those presented in the topical report.

3.3 Include a summary of significant RAIs and corresponding responses in the appropriate sections of the TER. Extended quotations or historical accounts are not necessary; rather, a concise description of the issue, its significance, and its resolution is the objective.

3.4. Document the basis for acceptability of the methodology. Technical and regulatory conclusions must be justified by adequate evidence and logical reasoning.

4.0 Conclusion

Clearly define any limitation or conditions related to the future application of the methodology.