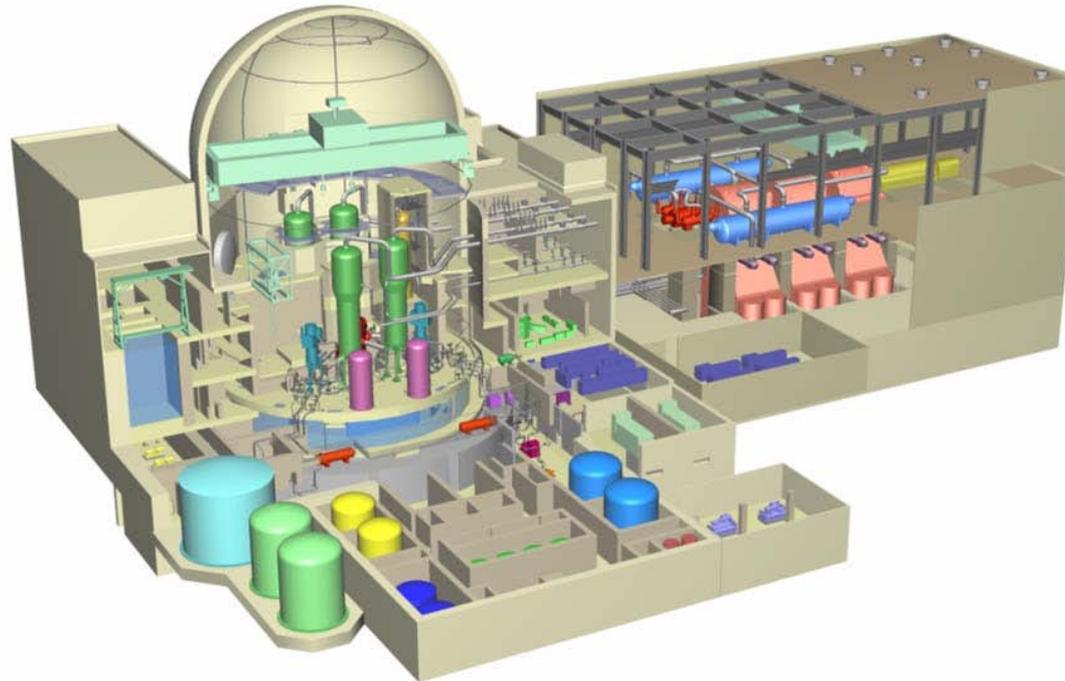


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**US-APWR**

# MELCO QA Audits and Corrective Actions



**September 30, 2010**



# MELCO QA Audits (by MHI)

## ➤ **March 2009:**

- Scope: MELTAC Development (not production activities)
- Basic Result: MELCO **has not** established a QA program based on 10CFR50 Appendix B

## ➤ **December 2009:**

- Scope: Phase I (Design and development only; not production activities)
- Basic Result: MELCO **has** established a QAP based on 10CFR50 Appendix B, 10CFR21, and NQA-1

## ➤ **May 2010:**

- Scope: Phase II (Procurement and Production)
- Basic Result: MELCO QAP **complies** with 10CFR50 Appendix B, 10CFR21, and NQA-1

**MNES has participated in audits, surveillances, and CA reviews**

# March 2009 Audit



**Result:** MELCO has not established a QAP based on 10CFR50 Appendix B

Findings		Corrective Actions	Status
1	Inadequate document identification	Review all MELTAC-NplusS documents (500+)	4
		Develop Appendix B QAP	
2	After V&V, no evaluation of effects of software specification changes	Create "change control sheet" to identify affected SW design documents	4
		Check for effect on SW code or unit tests	
		Develop Appendix B QAP	
3	Inadequate "preparer" qualification record	Check for properly qualified people on all docs	4
		Assess skills of people not on the Qualified Personnel List	
		Check remaining documents	
4-1	No independent design review of hardware	Develop RTM for all MELTAC-NplusS hardware	4
4-2	No V&V of Category 2 software	Independent V&V of Category 2 software	4
		Develop Appendix B QAP	

**Status:** 1) CA in progress (e.g., procedure being revised); 2) CA implemented (e.g., procedure issued); 3) CA Report approved by MELCO QA; 4) CA Report approved by MHI QA

# December 2009 Audit (1/2)



**Result:** MELCO has established a QAP based on 10CFR50 App. B, 10CFR21, and NQA-1

Findings		Corrective Actions	Status
1	Procedure conflict re: Hold Points	QAP Clarification	4
2	Procedure conflict re: qualification test as a design verification method	QAP Clarification	4
3	Inadequate procedure guidance for noting "no comments"	QAP Clarification	4
		Re-review affected documents	
4	Inadequate procedure guidance for review of design changes	Procedure changes	4
5	Incomplete application of FPGA test procedure	Procedure changes	4
		Revise FPGA test spec & report	
6	FPGA test prerequisites and criteria not clear	Procedure change	4
		Revise FPGA test spec	

**Status:** 1) CA in progress (e.g., procedure being revised); 2) CA implemented (e.g., procedure issued); 3) CA Report approved by MELCO QA; 4) CA Report approved by MHI QA

# December 2009 Audit (2/2)



Findings		Corrective Actions	Status
7	Procedure conflict re: evaluation of V&V anomalies	QAP Clarification	4
8	Incomplete application of test procedure	QAP Clarification	4
		Revise FPGA test spec & report	
9	Procedure inconsistencies, conflicts or translation issues <b>(including procedures that govern MRP)</b>	QAP Clarifications	3*
10	Management reporting procedure not clear	QAP Clarification	4
11	Part 21 posting, safety review team procedures not clear	QAP Clarification	4
12	Qualifications of FPGA V&V people not clear for prep/check/approve	QAP Clarification	4
		Revise FPGA V&V report	

\*Status 4 ECD:  
10/1/10

**Status:** 1) CA in progress (e.g., procedure being revised); 2) CA implemented (e.g., procedure issued); 3) CA Report approved by MELCO QA; 4) CA Report approved by MHI QA

# May 2010 Audit (1/2)



**Result:** MELCO QAP complies with 10CFR50 Appendix B, 10CFR21, and NQA-1

Findings		Corrective Actions	Status
1	CGD procedure does not include supplier surveys	Procedure change	1*
2	Some part "travelers" were missing	QAP clarification	1*
		Check other parts for missing travelers	
3	Incomplete record of test results	QAP clarification	1*
4	No program for identifying suspect material	Procedure development	1*
5	Thermo-hygrometer not calibrated	Implement calibration controls for storage monitoring devices	1*

\*Through Status 4  
by 1Q11

**Status:** 1) CA in progress (e.g., procedure being revised); 2) CA implemented (e.g., procedure issued);  
3) CA Report approved by MELCO QA; 4) CA Report approved by MHI QA

# May 2010 Audit (2/2)



Findings		Corrective Actions	Status
6	Missing signatures on two "pilot run" documents	QAP clarification	1*
		Delete "pilot run" documents	
7	Some manufacturing documents not properly controlled	QAP clarification	1*
		Revise affected documents	
8	Procedure conflict re: Non-conforming items	QAP Clarification	1*
9	One (of eight) Part 21 postings was not current	Update posting	1*
		QAP Clarification	
10	Three (of eight) Part 21 postings were not conspicuous enough	Relocate postings	1*
		QAP Clarification	

\*Through Status 4 by 1Q11

**Status:** 1) CA in progress (e.g., procedure being revised); 2) CA implemented (e.g., procedure issued); 3) CA Report approved by MELCO QA; 4) CA Report approved by MHI QA

# MELTAC Re-evaluation Program (MRP)



- August 2009: Letter to NRC – MRP will begin after MHI audit in December 2009
  - **1/28/10:** MHI audit report issued (with findings)
  - **3/4/10:** MELCO QA approved revised procedures that implement CA and govern MRP activities
  - **3/11/10:** MRP work initiated **based on approved QAP**
  - **7/20/10:** MRP report Rev. 0 submitted for NRC Review
- However, MELCO QAP states work that depends on implementation of CAs cannot proceed until CAR is approved by auditing organization (if requested; MHI QA in this case)
- MHI QA is currently reviewing CAR