

ARPANSA Regulatory Assessment of the Replacement Reactor Construction Application

18 July 2001- Reactive Review Questions and Issues

PSAR Chapter 18 Quality Assurance

Question Reference	Section number and name	Topic	ARPANSA Comment, Issue or Question and ANSTO's Response
18.1.	18.1 Introduction	<p>The Objectives of Chapter 18...</p> <p>b) To establish the framework to transition from the Facility Licence, Construction Authorisation to the Facility Licence, Construction Authorisation, including Stage B1, B2 and C Commissioning and the conduct of Contract Performance Demonstration Tests, the parallel operation with HIFAR, and the normal operating cycle following the completion of all commissioning and testing activities.</p>	<p>ARPANSA expects that the framework for the transition from construction to operation would be established in the management plans and that the quality assurance system supports these plans by ensuring that experience/changes are appropriately recorded and incorporated into the operating arrangements.</p> <p>It would appear that the scope of Chapter 18 is much more than just quality assurance.</p>
			<p>Response: The implementation of the transition from construction to operation will be achieved through the Contract Management Plans within the framework of the Contract Project Quality Assurance Program (PQAP). Under these arrangements, experience gained and changes made as a result of the design and construction phases, will be captured, recorded and incorporated into the operating arrangements.</p>
18.2.	18.2.1 ANSTO	<p>This certification covers the Quality Management System for the Project Management.</p>	<p>The quality management system is called the ANSTO Replacement Research Reactor Project (RRRP) Quality System (not the "Quality Management System" as suggested in this statement). A requirement of quality assurance should be consistency in terminology. It is noted that a definition of the Quality Management System is not contained in the Glossary.</p> <p>ANSTO PSAR Background Documents do not list the ANSTO RRRP Quality System documents.</p>

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			<p>Response: Whilst the quality management system is entitled "RRRP Phase 3 – ANSTO RRRP Quality System", the certificate of registration refers to the fact that "The registration covers the Quality Management System for the (ANSTO) project management of the ANSTO Replacement Research Reactor Project".</p> <p>Noting your comment regarding consistency of terminology, we propose to amend the title of ANSTO's system to read "RRRP Phase 3 – ANSTO RRRP Quality Management System" and in so doing, reflect more closely the intent of certification.</p> <p>The glossary will be updated to satisfy the comments raised.</p>
18.3.	18.2.3. John Holland Evans Deakin Industries Joint Venture	The JHEDI Quality System is an extension of the John Holland System with project specific procedures to cover aspects of Documentation Security, Documentation Control and Procurement Management.	What is meant by the phrase "The JHEDI Quality System is an extension of the John Holland System"? Does Evans Deakin Industries have a quality assurance system consistent with ISO9001:1994? What is Connell Wagner's level of quality assurance?

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			<p>Response: John Holland, one of the operative partners of JHEDI JV, has a certified quality management system to ISO 9001:1994. JHEDI JV has adopted John Holland's quality management system documents. In addition, project specific procedures have been developed by JHEDI JV for the RRRP Project.</p> <p>Ralph M Lee, the nominated operating subsidiary of Evans Deakin Industries for the purposes of this project, has a certified quality management system to ISO 9001:1994.</p> <p>JHEDI JV, therefore, has a quality management system consistent with ISO9001:1994. John Holland conducted an audit on JHEDI JV in March 01. A third party audit on JHEDI JV by Lloyd's Register Quality Assurance is scheduled to be conducted in November 2001.</p> <p>Connell Wagner has a certified quality management system to ISO 9001:1994.</p>
18.4.	18.2.4.2. External Audits	In the case of INVAP twice yearly quarterly external audits are undertaken by Bureau Veritas Quality International (BVQI).	Please confirm the time period for external audits of INVAP QA System.
			<p>Response: Bureau Veritas Quality International (BVQI) conducts six-monthly surveillance audits on INVAP followed by a re-certification audit once in every 3 years. In addition and as provided for in the Contract, ANSTO will conduct a third party audit on INVAP annually or at a greater frequency if considered necessary by the RRRP Project Manager. Det Norske Veritas conducted the first third party audit in February 2001. The audit report has been provided to ARPANSA.</p>
18.5.	18.2.4.3 Surveillance Audits	QAS will undertake a Surveillance Audit of the ANSTO RRRP Quality System ("quality system") in November 2001.	How does a Surveillance Audit differ from an External Audit?

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			<p>Response: A surveillance audit is an external audit conducted by certification bodies, following the initial certification audit, on a 6 monthly basis and forms part of the audit cycle. A re-certification audit will be conducted once every three years. The first surveillance audit following certification will be conducted by QAS in November 2001.</p>
18.6.	18.2.4.3 Surveillance Audits	ARPANSA will also be invited to attend each audit as an observer.	<p>Will ARPANSA be invited to all QA Audits (Internal, External and Surveillance)? Is this invitation detailed in the RRRP QA Manual?</p>
			<p>Response: The invitation is not detailed in the RRRP QA Manual, as there is no specific requirement to do so. Invitations have always been extended to ARPANSA in the past for participation in all the internal audits conducted by ANSTO. With the concurrence of QAS, ARPANSA will be invited to participate as an observer in all future surveillance audits by QAS.</p>
18.7.	18.2.4.3 Surveillance Audits	In relation to JHEDI, INVAP has planned to conduct a third party audit in June/July 2001. ANSTO will participate in that audit as an observer.	<p>When will this audit take place? Will ARPANSA be invited?</p>
			<p>Response: This audit has already taken place on 15/6/01. ANSTO participated in the audit as an observer. ANSTO will recommend to INVAP that ARPANSA be extended an invitation to attend all third party audits that are conducted on JHEDI JV in the future. ANSTO will also provide the resultant audit reports to ARPANSA.</p>

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18.8.	18.3.1 ANSTO	<p>The project manager... is responsible for ANSTO's compliance with, and maintenance of, the quality system.</p> <p>The chairman of the Project Monitoring Group (PMG) also has oversight of Quality Management.</p>	<p>The responsibilities of the Project Manager and the Project Monitoring Group detailed in RRP 1.2 (rev 3) do not support these statements. Please clarify.</p>
			<p>Response: Comment Noted. RRP 1.2 will be revised to support the statements made in the PSAR Chapter 18.</p>
18.9.	18.3.2 INVAP	<p>INVAP has established a Project Quality Assurance Program specifically for the design, construction and commissioning of the Reactor Facility.</p>	<p>Please provide a Table of Contents for the Project Quality Assurance Program.</p> <p>Please provide a listing of procedures that exist under this program.</p>
			<p>Response: The Table of Contents will be provided together with a listing of procedures.</p>
18.10	18.3.4 Project Management and Integration	<p>A link has also been established directly between ANSTO and JHEDI to facilitate progress, albeit within a controlled and transparent manner as described in the Communications Protocol.</p>	<p>1) There is no reference provided for the Communications Protocol document.</p> <p>2) There are no references to any supporting documentation. This appears to be a general finding for the entire PSAR.</p> <p>3) Please provide a listing of reference documents for each PSAR Chapter.</p>
			<p>Response:</p> <p>1) The Communications Protocol is identified as ANSTO Procedure RRP 9.3, forming part of the RRRP Phase 3 certified ANSTO RRRP Quality System.</p> <p>2 and 3) See response to comment 1.1. A list of references for each Chapter will be provided where it is appropriate.</p>

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18.11	18.3.4 Project Management and Integration	In the event of any uncertainty, the relevant staff member immediately seeks and receives the support of his/her immediate supervisor.	The Communications Protocol does not state this. It details the method of recording the communication between the parties. The statement that a staff member "immediately seeks and receives" requires further explanation.
			Response: The Communications Protocol will be revised to clarify the current practice, ie that in the event of any uncertainty, the participants will be required to seek the support of their supervisor who will provide the required support. If the immediate supervisor is not able to provide the required support, the matter will be brought to the attention of the RRRP Project Manager for support and advice.
18.12	18.3.4 Project Management and Integration	The conduct of regular, twice weekly tele-conferences between the respective project managers and selected team members.	Does the Communication Protocol cover all communications (including tele-conferences) or only telephone conversations? Are Minutes recorded for tele-conferences?
			Response: The Communications Protocol is intended to address all communications between the respective participants identified in the protocol. Twice weekly telephone-conferences between the respective Project Managers, including selected team members are recorded, when required, and files are maintained by each Project Manager. Where actions arise from these meetings, they are tasked to specific staff members for clearing of the actions.
18.13	18.3.5 Risk Management	The INVAP/JHEDI Risk Management Plan is formally updated by INVAP and audited by ANSTO on a quarterly basis.	Is this stated in the RRRP Quality System documents? Please provide reference.
			Response: RRP 9.1 Rev.1 will be revised to make provision for the quarterly updating by INVAP and auditing by ANSTO of the Contract (INVAP/JHEDI) Risk Management Plan.

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18.14	18.4.1 Post Contract up to Facility Licence Construction Authorisation	<p>This period involves the following activities:</p> <p>Development of the detailed design and engineering Contract deliverables.</p> <p>Development of the Construction Inspection and Test Plan.</p> <p>Delivery of Principal Furnished Materiel (PFM) by ANSTO to INVAP.</p>	<p>1) There appears to be no commitment of resources for addressing the Licence Application review process conducted by ARPANSA.</p> <p>2) ARPANSA would expect to see this addressed in the risk management plan.</p>
			<p>Response: Item (b) will be modified to read “ Development and Implementation of the Construction Inspection and Test Plan”. A new activity will be added at (d) that will read “Commitment of resources for addressing the licence application review process conducted by ARPANSA”.</p>
18.15	18.4.1.1 Detailed Design and Engineering Activities...	<p>... Stage A Commissioning activities which are the subject of the Construction Authorisation to be issued by the Regulator (ARPANSA).</p>	<p>A Construction Authorisation may be granted by the CEO of ARPANSA according to the ARPANS Act and Regulations. It would be more appropriate to state that ANSTO has made an application to the CEO of ARPANSA for a Construction Authorisation.</p>
			<p>Response: Noted; the sentence will be appropriately modified.</p>
18.16	18.4.1.1 Detailed Design and Engineering Activities...	<p>INVAP will provide ANSTO with updated details of the nature and planned date of release of discrete WP deliverables on a 6 month rolling window basis</p>	<p>Please explain the “6 month rolling window”.</p>

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			<p>Response: A rolling window is a longstanding, commonly used planning and scheduling tool to provide a progressively more detailed description of the content and delivery details of the Work Packages (WP) as they come closer to the time for delivery.</p> <p>The Detailed Engineering (DE) WP deliverables are spread over the period from February 2001 to December 2002, excluding the Simulator (WP 2.08.05), and DE-Safety Assessment and Licensing, Plant Documentation and ILS – refer Contract Master Schedule (CMS) rev 003, 26 April 2001.</p> <p>It is unreasonable to expect that the planning and scheduling details of the deliverables for each WP during the total DE phase will be available to the same degree of detail at all times throughout the phase. Emphasis therefore is placed by INVAP on firstly establishing the overall schedule for the WP's, ie the CMS, and secondly, to concentrate on the period 6 months out, to give better definition to the actual details of the deliverables being prepared, and when they will be issued, ie to update and refine the information on a rolling basis.</p> <p>The 6 month rolling window itself is divided into two periods of three months, the period closest to the actual delivery date receiving the maximum amount of attention to ensure that all recipients of the process, including ARPANSA, are well informed of the program.</p> <p>The rolling window is reviewed by INVAP on a weekly basis. ANSTO is provided with an update on a monthly basis only if there are significant changes impacting the project.</p>

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18.17	18.4.1.1 Detailed Design and Engineering Activities...	The ANSTO Director, Safety, will ensure that a representative of his Division participates in every such review...	Responsibility attributed to Director, Safety Division. There is no mention of the responsibilities of the Director, Safety Division in any QA documentation.
			Response: The ANSTO Director, Safety appoints the Safety & Licensing Manager, reviews the implementation of the integrated PSAR review process, provides resources to the Project Management Core Team (PMCT) for review of safety issues, makes decisions in respect of safety issues, and is the primary interface with ARPANSA. The ANSTO Director, Safety is an active member of the Project Monitoring Group (PMG). These functions are described in RRP 1.2, RRP 9.1-2, RRP 9.2 & RRP 9.4 and the role and duties of the ANSTO Director, Safety will be clarified in these procedures.
18.18	18.4.1.1 Detailed Design and Engineering Activities...	Upon the satisfactory conclusion of (2), ANSTO will indicate its acceptance of the design deliverables to INVAP and to ARPANSA, on the basis that they have been prepared in accordance with the criteria already established.	Does "(2)" refer to Reactor Processes or should it be "(b)"? What are "design deliverables"? Please provide a listing of design deliverable for items that are important for safety. Why does ANSTO not indicate acceptance of all design deliverables to ARPANSA?

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Question Reference	Section number and name	Topic	ARPANSA Comment, Issue or Question and ANSTO's Response
			<p>Response: Instead of “(2)”, it should be “(b)”.</p> <p>Design deliverables are equivalent to “Contract Design Documents” that are defined as the drawings, the specifications and the data prepared by INVAP. Note that “Documents” are defined as “<i>any relevant document or software including, where appropriate, technical documents, such as drawings, documents, designs, calculations, specifications, samples, patterns, models, reports, operation and maintenance manuals, other manuals, records and information of a similar nature including those produced by or contained within data processing systems</i>”.</p> <p>A list of design deliverables will be made available to ARPANSA in conjunction with the Contract Master Schedule.</p>
18.19	18.4.1.2 Provision of Principal Furnished Materiel (PFM) by ANSTO	The ANSTO Engineering Division is managing the delivery of the PFM on behalf of the project manager.	<p>ANSTO Engineering Division is effectively a Subcontractor however there is no mention of its quality assurance provisions.</p> <p>Does ANSTO Engineering have QA certification for the provision of services?</p>
			<p>Response: The role of ANSTO Engineering as a Supplier to the RRR Project Management Core Team is described in QM iii of the Quality Manual.</p> <p>ANSTO Engineering Quality Management System has had certification by Quality Assurance Services since 1993. The certification covers engineering project management, design, manufacturing, maintenance and quality control services for the provision of equipment, facilities and buildings for scientific and industrial purposes.</p>

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18.20	18.4.2 Construction Authorisation	The activities included in the period of the Construction Authorisation include: manufacturing and procurement, site construction, site installation, Stage A Commissioning, and completion of the detailed design and engineering, including the preparation of inspection and test documentation.	ARPANSA would expect to see a commitment to addressing the Licence Conditions that would be part of a Facility Licence – Authorisation to Construct.
			Response: Item f) will be added as follows: f) To address the Licence Conditions that would be part of a Facility Licence – Authorisation to Construct.
18.21	18.4.2.2 Manufacturing and Procurement	INVAP shall provide unpriced copies of all orders to ANSTO to verify that the PQAP conditions have been included. This documentation shall be made available upon request to ARPANSA	Please provide all information relevant to the system performance requirements of items that are important for safety as the information becomes available. Please provide a plan for the submission of details to ARPANSA for the approval of items important for safety.
			Response: ANSTO confirms that it will provide all information and arrange appropriate meetings to discuss the implementation of ARPANS Regulation 54 and the CITP/SITPs.
18.22	18.4.2.2 Manufacturing and Procurement	INVAP's manufacturing and procurement quality assurance provisions in the PQAP will be externally audited by ANSTO during the course of the program.	What are ANSTO's auditing actions to ensure that the items "as manufactured" meet the system requirements? Are the hold points during manufacture provided for in the CITP? Have allowances been made for ARPANSA inspections during Manufacture and Procurement?

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			<p>Response: There is provision in the CITP for incorporation of ANSTO hold and witness points as well as those identified by ARPANSA. These will be indicated in the Contract Master Schedule after details are mature. The details of ANSTO hold and witness points will be determined in conjunction with INVAP as the details of the program are developed as part of the current arrangements and being implemented by ANSTO RRRP Testing and Trials Manager. The ARPANSA hold and witness points will be agreed at meetings to be arranged (refer our response to Comment 18.21 above).</p>
18.23	18.4.2.5 Parallel Operations with HIFAR	...specific training is undertaken as required by the respective Quality Management Systems.	<p>Specific training should be based upon system requirements, not the quality assurance system.</p> <p>The Plant operating and maintenance manuals should specify training requirements.</p>
			<p>Response: ANSTO agrees that specific training will be based upon system requirements. The Operating and Maintenance Manuals will be developed co-jointly by INVAP and ANSTO. Operator and maintenance training will be conducted on these manuals in an advanced draft form. In this way, training will assist in the validation of the Operating and Maintenance Manuals. Please also refer to the responses provided to training related comments in Chapter 15: Commissioning.</p>
18.24	18.4.3.5.2 Operations and Maintenance Documentation	ANSTO will adopt the approach whereby INVAP will prepare the documentation to enable training to be conducted on the content of the Manuals, ie. the training program will validate the quality of the documentation provided.	<p>Where will the production and validation of the manuals be with respect to the commissioning of the plant?</p> <p>Will ANSTO personnel be involved in the preparation of the documentation?</p>

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			<p>Response: Commissioning documents will be prepared by INVAP, in consultation with ANSTO staff prior to commissioning. Their validation will be performed during the commissioning phase.</p> <p>ANSTO personnel will be involved in the preparation of the documentation.</p>
18.25	18.5 Summary	As required under the Contract, a Facility Quality Management System will also be developed to cover the routine operation and maintenance of the Reactor Facility at the conclusion of the Contract.	<p>It would be expected that the Facility quality assurance system would evolve from the RRRP quality system.</p> <p>Is the Facility quality assurance system really a deliverable at the “conclusion of the Contract” or to be operating at the time of Commissioning?</p>
			<p>Response: The Facility Quality Management System will be developed from experience gained from the operation of the Contract Project Quality Assurance Program (PQAP), the current HIFAR Quality Management System, the RRRP Quality Management System, and the draft Final Safety Analysis Report (FSAR).</p> <p>It is expected that the Facility Quality Management System will be in an advanced draft form at the time of commencement of commissioning. The experiences gained during commissioning and completion of the Final Safety Analysis Report (FSAR) will be employed to fine-tune the Facility Quality Management System.</p>