Questions Posted in Meeting - 7th Review Meeting (27 March - 7 April 2017)

No.	Posted By	Article	Ref. in Nat Report	Question / Comment	Answer
1	Euratom	Article 8.1	Page 13	Have other measures, different from the short-term contractual arrangements and resources re-allocation, been implemented/considered in order to reinforce the Regulatory Services Branch's staff, in particular in the long term? Could you explain the graded, risk-informed approach used? / As regards human resources and competences it is stated that: "in the past three years, the Regulatory Services Branch staff numbers have decreased from 28 to 23, due to retirements and resignations. The shortfall is being made up through short-term contractual arrangements and by allocating resources to inspection and compliance monitoring using a graded, risk-informed approach."	It has been challenging to implement measures other than short-term contractual arrangements or reallocation of resources in order to reinforce the Regulatory Services Branch staffing level in the longer term. ARPANSA is bound by Australian government policy that has stipulated that our organisation must operate with an average staffing level (ASL) of 130 across the organisation from July 2017. (Please see response to question 12 above for more information on the ASL). As a consequence of the ASL, if additional resources are required to meet work demand, short-term contractual arrangements and allocation of resources to inspection and compliance monitoring using a graded, risk-informed approach are the main approaches that can be employed. The graded, risk informed approach to inspection and compliance monitoring is laid out in the following documentation http://www.arpansa.gov.au/Regulation/goodregulatorypractice/index.cfm The graded approach applies to all aspects of regulation. It applies to the assessment of an application reviewed for a proposed change, or permission to construct an item import to safety. The graded approach is also taken with respect to the scope and extent of an inspection. Even the application of augmented inspection and enforcement is approached in a step-wise fashion and is informed by risk. ARPANSA regulates a wide variety of facilities and sources. A one-size-fits-all approach would be inappropriate. Regulatory resources applied to a task should be commensurate with the safety risks involved. The time and resources devoted to an inspection, or to the review of an application, depend on the nature of the facility or source. On one extreme is a nuclear reactor, on the other a small radioactive source. The baseline inspection regime for the nuclear reactor might involve eight or more separate inspections over three years, each of which may last up to two weeks and involved three or four inspectors. The user of the source, on the other hand, might expect one inspection by two individuals over the course of the baseline period. For source inspections, the inherent hazard categorisation of sources (Schedule 3C, Part 1 of the Regulations) is used to set the Regulatory Priority (RP). In summary, the lower risk sources have less resource devoted to them, which allows more resource to be allocated to higher risk sources and hence the graded, risk-informed approach. This is also a more efficient use of regulatory resources.

2	Euratom	Article 18.3	Page 30	Could you further explain how elements covered by principle 1 of the Vienna Declaration, namely the prevention of accidents during the commissioning and operations phase, have already been taken into account in particular to avoid off-site contamination? / As regards the implementation of principle 1 of the Vienna Declaration in respect of the Open Pool Australia Light-water reactor (OPAL reactor), it is stated that "the siting, design and construction of OPAL took into account the elements covered by Principle 1 of the Vienna Declaration, namely, the prevention of accidents during the commissioning and operations phase."	The Defence-in-Depth approach was used throughout the design of the OPAL reactor, including the prevention of accidents, examples of which include: • Fixed core with no in-core irradiation or test positions prevents accidents associated with such facilities. • No bank withdrawal of control rods and inherent physical limits on control rod withdrawal speeds prevents BORAX-type accidents. No high energy (high pressure or high temperature) systems eliminates potential for associated accidents involving, for example, pipe whip, missiles.

3	United States of America	Article 16	Emergency Preparedness/ Section 16.3	ARPANSA inspectors observe the emergency exercises conducted at the OPAL reactor. Do representatives from the State of New South Wales observe or participate in the emergency exercises conducted at the OPAL reactor?	Yes. Members of the NSW emergency service organisations often observe and or participate in exercises conducted at OPAL. The level of participation is dependent on the scenario construct and objectives. Notification of all exercises including invitations to members of the state ESO's are provided at local and regional emergency management committee meetings and at the state CBRN HAZMAT Committee meeting (particularly for major exercises).
4	United States of America	Article 16	Emergency Preparedness/ Section 16.5	In the past three years, there have been three major emergency exercises conducted at the OPAL reactor. (1) Have lessons learned from these exercises been incorporated into the ANSTO Emergency Response Plan? (2) Have lessons learned been incorporated into the emergency plans of the State of New South Wales?	The ANSTO EM plan requires that a review of the current plans and arrangements be undertaken post event or exercise and procedural improvements be incorporated where appropriate. Furthermore, in accordance with emergency management best practices, exercise management includes a briefing element which enables all stakeholders to address any issues and opportunities for improvement. ANSTOs EM Plan meets the requirements of the NSW State Emergency and Rescue Management Act (1987). The ANSTO Plan ensures there are clear escalation pathways and pre-established C3 elements (Command, Control and Communication) that are interoperable and consistent with NSW emergency arrangements. In regards to Q2. Operational SOPs for responding ESOs are routinely reviewed by the respective agency to ensure they are consistent and interoperable with ANSTO arrangements and are current with ANSTOs capabilities and command and control elements.

5	United States of America	Article 6	Section 6.7	Proposed good performance: Since 2006, ANSTO has participated in a collaborative agreement with operators of the SAFARI-1 reactor (South Africa) and the High Flux Reactor (The Netherlands). This aim of this agreement is to work together to increase safety and reliability through cooperation, as OPAL, SAFARI-1, and the High Flux Reactor are similar reactors. Meetings are held every 12 months to 18 months to exchange ideas, experiences, and good practices. This is an example of how Australia meets Challenge 3, identified at the 6th Review meeting, and how this country makes better use of operating and regulatory experience.	The comment is appreciated. Note that the collaboration between OPAL, SAFARI-1 and HFR is also intended to ensure the safety and reliability of Mo-99 supplies to the world-wide market.

6	Norway	Article 14.1	23	Under article 14 ARPANSA's program for inspections and site visits is mentioned. How many inspections, both announced and unannounced, per year are ARPANSA performing at ANSTO? How many site visits are undertaken?	Under the new Regulatory Delivery model, a risk-informed baseline inspection program defines the minimum level of planned inspections to evaluate performance over a defined period. Additional inspections including augmented ones are scheduled as needed. The risk rankings are reviewed annually and following inspections/breaches etc. A facility therefore with a risk ranking of very high will be inspected at least annually and at least 5 site visits conducted annually. Approximately 20 inspections are planned to be conducted at ANSTO in the period from 1 January 2017 – 31 December 2017, but this includes all facilities at ANSTO including radioisotope production facilities, radioactive waste stores, linear accelerators etc.
7	Norway	Article 15	page 25	Under article 15 it is reported that the doses at OPAL are typically low. What is the average annual dose, and the highest dose?	For 2016 the OPAL average dose was 0.69 mSv and the maximum 1.53 mSv
8	Norway	Article 16.1	page 26	Under article 16 it is reported that there has been performed assessments of the radiological consequences of acts of sabotage and terrorism at OPAL site, and that there is adequate protection of the public. What about the consequences for the workers at the OPAL site?	The assessment of radiological consequences arising from aircraft impact has been performed for OPAL by competent authorities. This information is classified and does not appear in any OPAL documentation. The OPAL Reference Accident assessed the suitability of the site in relation to offsite doses and does not include an assessment of onsite doses.

9	Peru	Article 6	Number 4, Page 6	May you describe the most important results of this self-assessment? / Under the Regulator Performance Framework, a self-assessment was undertaken on how regulators have administered regulation fairly, effectively and efficiently.	Noted with thanks. The first self-assessment was conducted in July 2016 and will be conducted annually. Actions are currently being implemented. The scope covered a review of ARPANSA's performance against the Government's Key Performance Indicators (KPIs) for Regulators. Please see summary of the outcomes below. See ARPANSA Website for a copy of the review: http://www.arpansa.gov.au/AboutUs/corporate/regperformance.cfm
10	Peru	Article 8.1	Number 9, Page 7 and Page 15	What are the main features of the new Delivery Model? / The new Delivery Model has allowed improving regulatory effectiveness and efficiency.	The Delivery Model is available on the ARPANSA website: http://www.arpansa.gov.au/Regulation/goodregulatorypractice/index.cfm Salient features of the new delivery model are as follows: The model lays out the approach to effective and efficient regulation, including the use of risk-based oversight and risk-informed decision making. The delivery model describes how limited resources can be optimised whilst enhancing radiation and nuclear safety. It also details a rigorous approach to inspection. The model focuses on regulatory inspection, and more specifically how RSB personnel are expected to go about assuring safe and secure operation by licence holders. This model is periodically reviewed and updated to reflect the RSB objective to continuously improve the performance of its regulatory services. As described in ARPANSA's Strategic Directions FY2014-2017, the regulatory approach assures safety by: • Emphasising to licence holders their special responsibility with respect to safety and security • Communicating with stakeholders in an open and transparent manner • Fostering a healthy and robust safety culture through collaboration with licence holders • Applying risk-informed approaches to licensing, inspection, and compliance activities • Taking appropriate and timely enforcement actions In addition to ensuring safety the model improves efficiency for both ARPANSA and licence holders. As set forth in Australia's Regulator Performance Framework of 2014, ARPANSA's delivery of regulatory services under the new model strives to: • Avoid unnecessary intervention in the operations of regulated entities • Communicate with regulated entities clearly and effectively • Take action proportionate to the regulatory risks being managed • Choose an approach to compliance and monitoring that is streamlined and coordinated • Remain open and transparent in dealings with regulated entities and the public • Perform frequent self-assessments in order to improve our delivery model

11	Peru	Article 10	Number 10.1, Page 17	Which are the Safety Culture elements that are considered by licence applicants or licence holder or accepted by regulatory body to demonstrate the commitment to a strong Safety Culture? / According the report, ARPANSA's requires applicants for a licence and licence holders to demonstrate a commitment to a strong safety culture.	ARPANSA's holistic safety guideline has been promoted to licence holders as a best practice approach to safety management. It is not used directly as a compliance tool however, ARPANSA expects licence holders to carefully consider its seven characteristics (human factors, non-technical skills, resilience, defence in depth, management system, safety culture and security culture) when developing work practices that are reflected in its management system. Aspects of the holistic safety approach are covered in other ARPANSA requirements such as the ARPANSA Regulatory Assessment Principles.
12	Peru	Article 11.1	Page 19	How practically ANSTO demonstrate the evidence of adequate resources and financial capability? / In the report is written that ANSTO must provide evidence of adequate resources, including financial capability.	Licence applicants must provide information as set out in the table in clause 1 of Schedule 3 to the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations) as part of their application. Reg 41 (e) requires the licence holders to have capacity to comply with regulations and licence conditions also. Part of this includes the provision of an Effective Control Plan which must demonstrate how the applicant will maintain effective control over the facility including management of issues such as organisational arrangements, management systems and resources. The Effective control plan forms part of the licencing basis and amendments must be preapproved by ARPANSA or reported retrospectively to ARPANSA, depending on their significance.

13	Peru	Article 12	Number 12.2 and 12.3, Page 21	How is inspected or qualified the resilience and the safety culture? Under which values or references are requested to make corrections if these characteristics are deemed failed? / According the report, key principles of holistic safety are arranged under seven 'characteristics', which are human aspects, non-technical skills, defense-in-depth, management system, resilience, safety culture, and security; human factors are covered in every inspection of the OPAL reactor.	Performance Objectives and Criteria (PO&C) are used by ARPANSA inspectors to support a consistent, transparent and rigorous approach to inspection that is consistent with the risk of a facility or source. PO&Cs provide a comprehensive list of features, controls and behaviours that contribute to safety. Three cross cutting areas of the PoCs cover safety culture. If a licensee is found to be lacking in an area of safety culture, the ARPANSA inspector may issue an Area for Improvement. This is not a legal requirement but ARPANSA encourages the licence holder to take action to address these areas for improvement. The licence holders' action on these areas for improvement is tracked by ARPANSA as part of a branch KPI.
14	Peru	Article 16.1	Number 16.11, Page 27	Which have been the most important or prioritized aspects and systems which were analyzed in the re-assessment? Some tests were performed (e.g. structure testing, etc.)? / The safety of OPAL has been re-assessed.	The safety of OPAL has been reassessed through a PSR in accordance with SSG-25 and subsequently through the safety reassessment in light of the Fukushima Daiichi NPP accident in accordance with IAEA SRS 80. The approach used in both cases was graded in accordance with SSG 22 with an emphasis on the Safety Category 1 SSCs and the design basis accidents in the case of the PSR and beyond design basis accidents and extreme external events in the case of the safety reassessment. No specific tests were performed as part of either the PSR or the safety reassessment.

15	India	Article 6	Sec 6.8, Page 10	Could Australia share the timeline for implementation of the same along with information on the scope, mechanism and criteria under consideration? / It is stated "At the time of writing of this report, a senior manager from the USNRC is a member of a panel that is assisting ARPANSA to undertake a self-assessment of its regulatory practices. This self-assessment is a requirement of the Australian Government under the Regulator Performance Framework that requires regulators to undertake annual self-assessment of their effectiveness and efficiency." It is a good initiative by Australia towards strengthening the regulatory framework.	Noted with thanks. The first self-assessment was conducted in July 2016 and will be conducted annually. Actions are currently being implemented. The scope covered a review of ARPANSA's performance against the Government's Key Performance Indicators (KPIs) for Regulators. Please see summary of the outcomes below. See ARPANSA Website for a copy of the review: http://www.arpansa.gov.au/AboutUs/corporate/regperformance.cfm

16	India	Article 10	Sec. 10.7, Page 18	It is stated that “ANSTO has, in consultation with ARPANSA established Safety Performance Indicators (SPIs) for OPAL. These SPIs measure and set objective targets for 22 safety related functions of plant operation and organizational performance…” Would Australia share the information on whether the outcome of assessment of SPIs is being used in the regulatory process? If so, kindly share the extent to which it is being used in the regulatory processes.	The outcome of the assessment of SPIs is not being use/shared in the regulatory process as there is only one nuclear installation in Australia which requires the use of SPIs (the OPAL Research Reactor).
17	Netherlands	General	page 6, summary	Which of the Recommendations from the IRRS mission are still not implemented and why, what is their current resolution planning?	The scope of the 2011 follow-up to the 2007 IRRS was broadened to include medical radiation protection. Remaining issues in this area are expected to be closed out with the new Medical Exposure Code, expected to be released for public consultation shortly. http://www.arpansa.gov.au/Regulation/Branch/irrsreview.cfm

18	Netherlands	General	summary	Could you please explain what are the most important actions that Australia will take based on the IAEA Fukushima summary report?	As detailed in the report, a safety reassessment of OPAL was performed in accordance with the guidance contained in IAEA SRS 80 and a number of recommendations were identified. However, most of these recommendations related to opportunities for improvement and there were none requiring immediate corrective actions. The EPR for ANSTO as a whole has also been subject to ongoing review and revision as part of our process for continuous improvement and lessons learned from the Fukushima Daiichi NPP accident have been taken into consideration as appropriate. ARPANSA's review of the OPAL PSR demonstrated that experiences from the accident had been considered and implementation of actions had resulted in improved safety margins. http://www.arpansa.gov.au/News/whatsnew/news1_141022.cfm
19	Netherlands	General	page 6, summary	Based on the guidance on periodic safety and security review: are these reviews combined safety/security reviews? And are they presented in one integrated report?	They were not presented as a single report as they were undertaken at different time periods. The next PSSR (to be finalised 2021) will be a combined review.
20	Netherlands	Article 8.1	8.1	Many regulatory bodies in the world, face the challenge to transfer knowledge of retiring or senior staff to younger and/or new staff. Is this also the case in your country? Do you have a dedicated program for knowledge transfer and do you provide trainings to senior staff to improve their skills in knowledge transfer?	The challenge of transfer of knowledge for the Regulator is also applicable to ARPANSA. RSB holds annual training on relevant regulatory matters. There is now a dedicated programme of lead and back up inspectors assigned to each facility/source so knowledge from the lead can be passed onto the back up at all times. ARPANSA also ensures rotation of inspectors so that all staff can gain experience in the wide range of areas which are regulated. ARPANSA also often recruits new staff from overseas countries with established nuclear programmes to maintain the skill set of the branch.

21	Netherlands	Article 8	page 7	The size of the RB dropped from 28 to 23 in three years. This was compensated by a risk informed approach and short hiring. Did you perform an analysis to establish the minimum size of the staff and the necessary competences that should be available to guarantee the robustness of the RB?	No analysis was undertaken to determine the minimum staff required in RSB. The drop in the size of the RSB from 28 to 23 occurred during a period of government restrictions on recruitment. At the end of this period there was a short time where recruitment was allowed with less restrictions, however from July 2016 the government imposed an 'average staffing level (ASL)' cap for the Commonwealth public service. See table below for ARPANSA's ASL cap. If we wish to increase staff numbers to more than 23 in RSB to ensure the robustness of the RSB, we are limited in options to access additional resources without trade-offs elsewhere in the organisation. Any shortfall is currently being made up through short-term contractual arrangements and by allocating resources to inspection and compliance monitoring using a graded, risk-informed approach. Additionally, under the recent exercise by ARPANSA to determine its compliance against ISO 17020, it has reviewed and updated its competences for inspectors and is currently introducing a Qualification Card system whereby all new inspectors will undergo competency checks in core areas for inspectors e.g. inspection and enforcement, nuclear installations, radiation protection, regulatory systems etc. These competencies are additional to the mandatory qualifications and skills of the inspectors.
22	Netherlands	Article 8	art.8	Are IAEA missions taking place at the OPAL reactor regularly (e.g. INSARR)?	No, to date, there have been no IAEA INSARR missions to the OPAL reactor. However, there have been IAEA Peer Review missions of both the application to construct and the operating application. In addition, OPAL directly organised an independent international peer review of the PSR in 2011.

23	Netherlands	Article 11	art.11	How does the regulatory body assess the sufficiency of human and financial resources at the nuclear installations?	Licence applicants must provide information as set out in the table in clause 1 of Schedule 3 to the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations) as part of their application. Reg 41 (e) requires the licence holders to have capacity to comply with regulations and licence conditions also. Part of this includes the provision of an Effective Control Plan which must demonstrate how the applicant will maintain effective control over the facility including management of issues such as organisational arrangements, management systems and resources. The Effective control plan forms part of the licencing basis and amendments must be preapproved by ARPANSA or reported retrospectively to ARPANSA, depending on their significance.
24	Netherlands	Article 12	art.12	Does the RB have its own safety and security culture programme? If so, what are the main characteristics of that programme?	ARPANSA does not a safety and security culture programme. However, ARPANSA has produced its own holistic safety guidelines for its Licence Holders which are placed on its website at: http://www.arpansa.gov.au/Regulation/Holistic/index.cfm These guidelines include organisational aspects such as safety culture. Aspects of safety culture and security are included in the inspection programme. The security and safety culture inspection modules can be found on the ARPANSA website at: http://www.arpansa.gov.au/Regulation/inspections/POandC.cfm
25	Netherlands	Article 14	page 23	The report mentions that modifications that have 'any' safety impact must be approved by the RB. Is this part of a graded approach?	The report refers to the OPAL internal Reactor Assessment Committee (RAC) approving modifications with any safety impact and not RSB. There is a graded approach since only changes with significant safety impact require approval by ARPANSA, whereas those changes with minor or no safety impact only have to be notified to ARPANSA.

26	Netherlands	Article 16	page 27	Please give the list of measures decided upon after the stress test.	As stated in the report, none of the recommendations arising from either the preliminary assessment or the formal safety reassessment require immediate corrective action but are instead opportunities for improvement. Most relate to extensions of the existing design basis and beyond design basis accident analysis to demonstrate the margins inherent in the OPAL design and operation. The only design modification (referred to in the report) has already been implemented.
27	India	Article 8.1	Sec. 8.6, Page13	It is stated "Although the RSB's full-time staffing level has decreased in the last three years, the shortfall is being managed by allocating resources to inspection and compliance monitoring using a graded, risk-informed approach. In January 2015, the RSB introduced a new Delivery Model to improve effectiveness and efficiency." Would Australia provide some salient features of the new Delivery model?	The Delivery Model is available on the ARPANSA website: http://www.arpansa.gov.au/Regulation/goodregulatorypractice/index.cfm Salient features of the new delivery model are as follows: The model lays out the approach to effective and efficient regulation, including the use of risk-based oversight and risk-informed decision making. The delivery model describes how limited resources can be optimised whilst enhancing radiation and nuclear safety. It also details a rigorous approach to inspection. The model focuses on regulatory inspection, and more specifically how RSB personnel are expected to go about assuring safe and secure operation by licence holders. This model is periodically reviewed and updated to reflect the RSB objective to continuously improve the performance of its regulatory services. As described in ARPANSA's Strategic Directions FY2014-2017, the regulatory approach assures safety by: • Emphasising to licence holders their special responsibility with respect to safety and security • Communicating with stakeholders in an open and transparent manner • Fostering a healthy and robust safety culture through collaboration with licence holders • Applying risk-informed approaches to licensing, inspection, and compliance activities • Taking appropriate and timely enforcement actions In addition to ensuring safety the model improves efficiency for both ARPANSA and licence holders. As set forth in Australia's Regulator Performance Framework of 2014, ARPANSA's delivery of regulatory services under the new model strives to: • Avoid unnecessary intervention in the operations of regulated entities • Communicate with regulated entities clearly and effectively • Take action proportionate to the regulatory risks being managed • Choose an approach to compliance and monitoring that is streamlined and coordinated • Remain open and transparent in dealings with regulated entities and the public • Perform frequent self-assessments in order to improve our delivery model

28	India	Article 14.1	Sec 14.11, Page 24	The first PSR report was submitted to ARPANSA in December 2011 and a further supplementary PSR report was submitted in June 2013. ARPANSA reviewed and accepted the PSR in October 2014. PSR process is an effective means adopted by Australia to keep safety provisions up dated. India is also following the similar mechanism and found to be extremely useful for safety up-gradation of operating NPPs.	Noted with thanks.

29	Switzerland	Article 10	Chapter 10.4 / page 17	In the report ANSTO's safety policy as well as its safety management and culture are described. Thereby measures that support a positive safety culture (i.e. business management system, risk management, quality management) are listed. Could you please outline your concept of safety culture and describe how, with the help of the measures set out in the report, a positive safety culture can be promoted and achieved.	the highest level within ANSTO, the ANSTO Corporate Plan includes safety culture as part of the overall organisation culture and this is developed and implemented throughout the organisation integral with our operational and business processes, including those within Nuclear Operations. As an example, a key indicator of safety performance is the number of opportunities for improvement identified, which is considered to be an essential component of a robust safety culture and a key driver for continuous safety improvement. Other examples include an ANSTO-wide monthly safety focus, an integrated safety event reporting and investigation system

30	Switzerland	Article 12	Summary p. 7	Switzerland noted with interest that ARPANSA has published guidelines on holistic (or systemic) safety to provide guidance on key technological, human and organizational aspects that are necessary to create and maintain optimal safety. We agree that safety has to be understood in a holistic (or systemic) view where technological, human and organizational aspects are seen both in their own rights as well as in terms of their interactions and interferences.	Noted with thanks.

31	Switzerland	Article 13	p. 22	How did the guideline on holistic saftey approach effected the improvement process of the Management System of the licensee holder and the oversight of hthe regulator? / ARPANSA has published information and guidelines on holistic (or systemic) safety to provide guidance on key technological, human, and organisational aspects that are necessary to create and maintain optimal safety.	ARPANSA's holistic safety guideline has been promoted to licence holders as a best practice approach to safety management. It is not used directly as a compliance tool however, ARPANSA expects licence holders to carefully consider its seven characteristics (human factors, non-technical skills, resilience, defence in depth, management system, safety culture and security culture) when developing work practices that are reflected in its management system. Some aspects of the holistic safety approach are covered in other ARPANSA requirements such as the ARPANSA Regulatory Assessment Principles. In the four years since ARPANSA launched the holistic safety guide, it has observed improved awareness of the impact of human and organisational factors for safety amongst licence holders. This is sometimes, but not always apparent, in the management system of licence holders, and is difficult to gauge. ARPANSA has continued to promote the holistic approach to safety during this time and has found good levels of interest from licence holders. ARPANSA has also integrated many aspects of the holistic safety approach into performance objectives and criteria (PO&C) which are used as the foundation for all inspections. Where a licence holder does not meet a PO&C which relates to holistic safety it may be issued with a finding of "area for improvement". ARPANSA expects licence holders to address and correct any areas for improvement and tracks any corrective actions. ARPANSA also has tools such as the use of improvement notices or the addition of licence conditions should a significant "area of improvement" fail to be adequately addressed by a licence holder. Using this multi-pronged approach ARPANSA is realising a gradual transition to improved awareness and practices in human and organisation factors.
32	Switzerland	Article 14	14.7-14.9	How are the inspections documented and how does the assessment methodology look like?	Performance Objectives and Criteria (PO&C) are used by ARPANSA inspectors to support a consistent, transparent and rigorous approach to inspection that is consistent with the risk of a facility or source. PO&Cs provide a comprehensive list of features, controls and behaviours that contribute to safety. When considered with relevant codes and standards the PO&Cs assist the detailed planning and conduct of each inspection and support a qualitative assessment of safety. Inspections are documented on a standard template and are available publically on the following link. http://www.arpansa.gov.au/regulation/inspections/reports.cfm

33	Switzerland	Article 15	Page 25	Are the EU BSS values the underlying basis? / There is no reference to dose limit values for occupationally exposed persons and the public given.	ARPANSA legislation uses the dose limits provided in Schedule III of IAEA GSR Part 3, which is consistent with the EU limits. The Code of Practice for Radiation Protection in Planned Exposure Situations (2016) was published in November 2016. http://www.arpansa.gov.au/pubs/rps/rpsc-1.pdf
34	Switzerland	Article 15	Page 25	How high are these values? What is the total annual collective dose and how many persons contribute? / It is mentioned that the doses associated with OPAL are typically low.	For 2016 the OPAL average dose was 0.69 mSv and the maximum 1.53 mSv. Approximately 120 people contributed.
35	Switzerland	Article 16	16.6., page 26	The report states that the current emergency plans and arrangements, including adoption of the WHO guidelines for the dissemination of iodine tablets, provide an adequate protection of the public. What is the strategy for storing and distributing the iodine tablets? Are iodine tablets predistributed to the public and if so, how far? What would be the trigger for ordering either intake or distribution of the tablets ?	ANSTO has sufficient supplies of emergency prophylaxis iodine tablets to protect all personnel on site. The ANSTO KI cache is situated in two strategic locations across site and accessible by key emergency personnel. Escalation protocols for distribution and authorisation for personnel to self-administer KI is detailed in Section 10.4 of the ANSTO Emergency Management Plan. Triggers for the administration of KI are based on recommendations described in ARPANSA Radiation Protection Series No 7. Distribution of prophylaxis iodine for members of the public in NSW (vicinity of the ANSTO site) is the responsibility of NSW Health Department. The department manages stockpile of stable iodine, strategically situated across several regional warehouses. The distribution and authorisation of the public cache is detailed in the NSW State Emergency Management Plans and Arrangements. Specifically, NSW CBRN/ HAZMAT Sub Plan - Lucas Heights Emergency Sub Plan - Lucas Heights Emergency Evacuation Sub Plan - Lucas Heights Strategy for Off-site Iodine distribution. NSW refer to the WHO “Guidelines for Iodine Prophylaxis following Nuclear Accident” for recommending appropriate triggers for public administration.

36	Switzerland	Article 16	16.9., page 27	The report states that during the Fukushima nuclear accident ARPANSA provided technical advice to the Australian Government and amongst other things modelled the movement of radioactive plumes. What dispersion modell has been used?	ARPANSA used the Accident Reporting and Guidance Operational System (ARGOS) as a decision support system during the Fukushima Dai-ichi nuclear power plant accident. The system includes the RIMPUFF (Risø Mesoscale PUFF model) atmospheric dispersion puff model, designed for calculating the concentration and doses resulting from the dispersion of airborne materials. http://www.arpansa.gov.au/pubs/technicalreports/tr150.pdf Atmospheric dispersion modelling was performed by ARPANSA in collaboration with University of Roma Tre in Italy to predict radiation levels in Australia. The FLEXPART Lagrangian particle model (Stohl et al. 2005) and European Centre for Medium-Range Weather Forecast weather data was used. The source term chosen was based on the work of Stohl et al. (2012).
37	Switzerland	Article 17	p. 28	How is the meteorology of the site taken into account for the design of the facility? / It is stated that the design of a facility should take the site's meteorology into account.	The meteorology of the site is covered under the site characteristics (Chapter 3 of the OPAL Safety Analyses Report) and is taken into account in the design of the facility through the application of the relevant codes and standards, particularly the various parts of Australian Standard 1170 in relation to design loads for civil structures.
38	Switzerland	Article 17	p. 28	How was the Reference Accident for earthquakes derived?	OPAL does not have a “Reference Accident for earthquakes”. A Reference Accident has been defined for OPAL that assumes melting of 25% of the core and degradation of the containment systems but this is not related to any specific earthquake event.
39	Switzerland	Article 8	P. 13, 8.6	Has the introduction of the Delivery Model changed the mode of operation for ARPANSA?	The introduction of the Delivery Model has changed the mode of operation for ARPANSA, mainly in the area of inspection and compliance monitoring. This has resulted in more predictability in outcomes for licence holders, and a more consistent approach by inspectors. In general, it has been received well by most ARPANSA licence holders.

40	Croatia	Article 8.1	Article 8, 13	In the past three years the RSB's staff numbers have decreased from 28 to 23 and the shortfall is being made up through short-term contractual arrangements and by introducing a graded approach. Is the long-term intention (a) to stay with present number of the employees, (b) to go back to 28 employees or (c) to further decrease the number of the employees?	There is no long-term intention to decrease the number of employees in RSB. ARPANSA is bound by Australian government policy that has stipulated that our organisation must operate with an average staffing level (ASL) of 130 across the organisation from July 2017. (Please see response to question 12 above for more information on the ASL). This currently equates to 23 staff in RSB. It should be emphasised that the decrease in the number of employees in the regulatory area was due to natural attrition and not a planned reduction in staff and occurred during a period of government restrictions on recruitment. As a consequence of the ASL, if additional resources are required to meet work demand, short-term contractual arrangements and allocation of resources to inspection and compliance monitoring using a graded, risk-informed approach are being employed.
41	Croatia	Article 8.1	Article 8, 13	Graded risk-informed approach was introduced in inspection and compliance monitoring areas. Are there any plans to introduce this approach also in authorization (licensing) and other areas?	The graded risk informed approach has always been applicable to licence applications. It is not currently necessary in other areas of RSB.
42	Croatia	Article 16.1	Article 16, 26	Are potential accidents at nuclear powered vessels included in the emergency plans? Have any exercises related to such accidents been organized so far?	As part of conditions of entry and approval of nuclear power vessels (warships) of each port, the Australian State and Territory will undertake a review of the emergency response plans. Emergency exercises are conducted.

43	Croatia	Article 16.1	Article 16, 26	Iodine tablets are mentioned in relation to OPAL. What is the general concept for the implementation of this protective measure? Have the tablets been predistributed?	LHSTC have sufficient supplies of emergency prophylaxis iodine tablets to protect all personnel on site. The ANSTO KI cache is situated in two strategic locations across site and accessible by key emergency personnel. The proximity of OPAL to on-site emergency response personnel and KI caches negates the need to pre-distribute KI. Escalation protocols for distribution and authorisation for personnel to self-administer KI is detailed in Section 10.4 of the ANSTO Emergency Management Plan. Triggers for the administration of KI are based on recommendations described in ARPANSA Radiation Protection Series No 7.
44	Ireland	General	N/A	Ireland thanks Australia for its comprehensive national report which is structured in accordance with the articles as given in the Convention and includes the perspectives of both the regulators and the operators.	Noted with thanks.
45	Ireland	Article 7.1	Section 7.5, p.6	Under the Australian Radiation Protection and Nuclear Safety Act 1998 (Amended 2015), which enables the regulation of the OPAL reactor, the CEO was provided with additional powers to direct a licence holder, issue improvement notices, and compel the provision of information. Has this additional power being used to date and was it effective?	To date these additional powers have not been required to be used.

46	Ireland	Article 7.1	Section 7.8, p.12	The Australian Radiation Protection and Nuclear Safety Act 1998 provides enforcement measures, which include cancellation or suspension of a licence, modification of a licence, issuing directions to a licensee, varying licence conditions, imposing additional licence conditions, or prosecution. Noting the graded approach to enforcement, has ARPANSA published an enforcement policy outlining the graded approach, general principles and decision architecture?	The ARPANSA Regulatory Services Compliance and Enforcement Manual outlines the risk ranking methodology, how to apply the graded approach and management of non-compliance. This is an internal guide used by the regulatory services branch staff. External guidance is provided to stakeholders in the Compliance & Enforcement Strategy REG-MAN-270 and the Regulatory Guide: Graded Response to non-compliance REG-COM-SUP-270J, both of which are published on the ARPANSA website. http://www.arpansa.gov.au/pubs/regulatory/licenceholders/REG-MAN-270.pdf http://www.arpansa.gov.au/pubs/regulatory/guides/REG-COM-SUP-270J.pdf

47	Ireland	Article 8.1	Secction 8, p7 & p13	In the past three years, the ARPANSA's Regulatory Services Branch's (RSB) staff numbers have decreased from 28 to 23 due to retirements and resignations. The shortfall is being made up through short-term contractual arrangements and by allocating resources to inspection and compliance monitoring using a graded, risk-informed approach. While noting the appointment of a Human Capital Manager to assist in workforce planning and development, and the use of a new Delivery Model to improve effectiveness and efficiency, is it likely in the foreseeable future with workforce planning that the staff of the RSB will be increased to a full complement?	The reduction in staff in the regulatory area has been due mainly to retirement and resignations. It should be emphasised that the decrease in the number of employees in the regulatory area was not a planned reduction in staff and occurred during a period of government restrictions on recruitment. Replacement has been complicated by two key factors: (a) ARPANSA is bound by Australian government policy that has stipulated that our organisation must operate with an average staffing level (ASL) of 130 across the organisation from July 2017. (Please see response to question 12 above for more information on the ASL). This currently equates to 23 staff in RSB; and (b) Shortages of appropriately skilled people in the workforce. At this stage it is difficult to predict if or when the staff numbers will increase again. As a consequence of the ASL, if additional resources are required to meet work demand, short-term contractual arrangements and allocation of resources to inspection and compliance monitoring using a graded, risk-informed approach is being employed.

48	Ireland	Article 8.1	Section 8.7; p 14	Noting that the RSB is working towards compliance with ISO 17020:2012 for inspection bodies, is it anticipated that full accreditation to the standard will be sought in the future or practical implementation of a quality management system in the first instance?	RSB is intending to comply with ISO 17020:2012 by 1 July 2017. There are no plans to apply for full accreditation any time in the near future.
49	Ireland	Article 16.1	Section 16.3; p 26	Emergency exercises at OPAL are witnessed by ARPANSA inspectors. How are these exercises evaluated and are lessons learned incorporated into OPAL's emergency plans?	In accordance with emergency management best practices, exercise management includes a briefing element which enables all stakeholders, including ARPANSA inspectors to address any issues and opportunities for improvement. Evaluation of exercises is undertaken using a range of established techniques. They include: • Specific pro-forma checklists addressing one or more objectives • External SME observations (particularly key members of emergency services organisations) • Internal SME observations (Internal Observers, including Safety Observers) • Debriefing Sessions (Hot Debrief, Formal Debrief and Agency Specific Debriefs) • objectives underpinned by measurable KPIs All feedback is considered invaluable and all opportunities for improvement are considered.

50	Ireland	Article 16.1	Section 16.6; p 26	Are iodine tablets pre-distributed to the public? If so, what is the radius around OPAL for distribution and how are they distributed?	ANSTO has sufficient supplies of emergency prophylaxis iodine tablets to protect all personnel on site. The ANSTO KI cache is situated in two strategic locations across site and accessible by key emergency personnel. Escalation protocols for distribution and authorisation for personnel to self-administer KI is detailed in Section 10.4 of the ANSTO Emergency Management Plan. Triggers for the administration of KI are based on recommendations described in ARPANSA Radiation Protection Series No 7. Distribution of prophylaxis iodine for members of the public in NSW (vicinity of the ANSTO site) is the responsibility of NSW Health Department. The department manages stockpile of stable iodine, strategically situated across several regional warehouses. The distribution and authorisation of the public cache is detailed in the NSW State Emergency Management Plans and Arrangements. Specifically, NSW CBRN/ HAZMAT Sub Plan - Lucas Heights Emergency Sub Plan - Lucas Heights Emergency Evacuation Sub Plan - Lucas Heights Strategy for Off-site Iodine distribution. NSW refer to the WHO “Guidelines for Iodine Prophylaxis following Nuclear Accident” for recommending appropriate triggers for public administration. Some comments: 1. Protective measures to members of the public will be guided by field measurements to implement appropriate operational intervention levels. 2. The distribution and or pre-distribution of stable iodine to the public are the responsibility of NSW State Health officials. ANSTO will provide SME advice to State decision makers in regards to OILS and relevant protective measures.
51	Ireland	Article 16.1	Section 16.9; p 27	Could further information be provided on the number of laboratories available to measure radioactivity in foodstuffs in Australia, whether they are accredited (and to what ISO standard)?	There are three organisations in Australia which ARPANSA is aware of which are currently accredited to ISO 17025 for measurement of radioactivity in food. These are: • ARPANSA • SGS Pty Ltd • Queensland Health There are other organisations such as ANSTO which have the capability, but are not accredited.

52	Ireland	General	N/A	Areas of Good Performance: Ireland considers the Implementation of a Quality Management System to ISO 17020:2012 as an area of good performance.	Noted with thanks.
53	Sri Lanka	General	page 5	In Page 5 under waste management (vii) indicated that intermediate level wastes that are temporarily stored in interim waste storage at ANSTO will be moved to planned National Radioactive Waste Management Facility when the facility is available. Can you inform us when this planned facility is made available for operation	There is no current date available for this facility which is still in the planning stages. There are currently three sites that have been nominated for consideration by the respective landholders. The Government is currently undertaking public consultation to gauge wider community support for these nominations. No decision will be made on a final site until a positive result is returned for these and other environmental and safety considerations.