Questions Posted to Australia- 8th Review Meeting

No.	Posted By	Article	Ref. in National Report	Question / Comment	Answer
1	Czech Republic	Article 16	Page 39/Section 16.3	The IRRS mission issued some recommendations in 2018. How did you focus on these recommendations and have any criteria or procedures already been developed?	Australia has developed a national action plan to provide strategic guidance and progress on implementation of the findings of the 2018 IRRS mission. The action plan contains a reporting matrix that separates findings and groups them by responsible bodies. ARPANSA coordinates input from multiple agencies and governments to populate progress reports for the action plan. Once the action plan has been agreed by all governments, it will be published publicly on ARPANSA's website and updated as progress occurs. For multi-jurisdictional findings, ARPANSA does not have sole responsibility for implementing them. The responsible body is the Environmental Health Standing Committee. For details about this committee, please see - https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-environ-enhealth-committee.htm This committee includes senior Health representatives from each State and Territory and the Federal government. The members have established a radiation protection expert reference panel to provide technical input into implementation. Reporting on progress against the IRRS findings is put into the action plan every six months. Findings addressed to the Australian Government have been allocated to the Commonwealth Department of Industry, Science, Energy and Resources. They have policy lead on the radioactive waste management facility and decommissioning. For findings addressed to ARPANSA, ARPANSA is able to directly provide input into the action plan. All findings addressed to ARPANSA have commenced implementation. Although none of the findings addressed to ARPANSA are fully implemented yet, most if not all should be complete or be able to be closed on the basis of progress and confidence by the follow up IRRS mission in 2022.
2	Germany	Article 14	p. 34	It is stated in the National Report that the SAR must include deterministic safety analyses and the probabilistic safety assessment may be used supplementary to assess the design-basis and beyond-design-basis accidents. Could Australia please inform whether there was already a probabilistic safety analysis performed for OPAL or HIFAR already? What is the practical experience with using probabilistic assessment in Australia?	An independent Level 1+ PSA was performed for HIFAR by consultants starting in 1996 with the resultant report issued in January 1998. Some of the information contained in this PSA was subsequently used as input into the OPAL PSA discussed in response to question 51, particularly in relation to external events.

3	Spain	Article 16	Pag. 41	Is there any procedure to control of radioactivity in the ports where these ships dock? / In page 41 it is said: “Whilst not a nuclear installation as defined under the CNS, Australia does receive visits by foreign nuclear powered warships and arrangements have been established including conditions of entry to ensure that the safety of the general public is maintained during visits by such vessels. The Australian Government requires emergency arrangements to be in place at all Australian ports visited by NPW in the unlikely event of a radiological emergency, including a requirement that there be the capability to undertake radiation monitoring of the port environment. The responsibility for the conduct of these procedures is shared between the Australian Government and State/Territory Governments”	The visiting ship owner (i.e. the Member State which owns the ship) is responsible for safety procedures aboard the vessel and the limitation of a radiological release. The Australian State or Territory and the Commonwealth (through the Royal Australian Navy, ARPANSA, designated State or Territory authorities, Department of Health, ANSTO and other agencies) are responsible for emergency preparedness and response (EPR) outside of the vessel. Arrangements for visits are organised through the Visiting Ships Panel (Nuclear) – a committee of representatives from all relevant stakeholders. EPR arrangements include; Port Validation, including reference accident simulations; Stable Iodine storage and distribution; Monitoring - Automated gamma-rate detectors are installed at ports that received visits from nuclear powered warships, viz. Brisbane and Perth. These detectors feed data to a Geographic Information System (GIS), and data obtained is intended for use to trigger emergency response procedures. Passive monitoring via OSL technology is also used to assess doses in the vicinity of the berth and post-visit environmental monitoring is conducted in the marine environment using a sea-water sampler. Further information on nuclear powered warship visit planning, associated procedures and reference accident is provided on the ARPANSA website at: https://www.arpansa.gov.au/research/radiation-emergency-preparedness-and-response/visits-by-nuclear-powered-warships
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5	Spain	Article 8	Page 23	Are ISO standards 9001 and 17020:2012 fully compatible with IAEA guidance on the subjects? How is integrated management system within ARPANSA improving its activities and performance? / ARPANSA is validating his Quality Management System against IS9001 as well as competence of inspection body against IO 17020:2012. The QMS is being integrated with the Integrated Management System under development across the agency.	Both ISO 9001 and ISO 17020 are standalone standards, and because of their need to be self-supporting, they are not directly compatible with the IAEA guides. The IAEA guides and the standards are both written around similar principles to the standards. This allows for interpretation of the standards and the application documents that satisfies both requirements of IAEA and ISO documents. ARPANSA was able to develop this interpretation by extensive document mapping (IAEA to ISO standards) with gap analysis carried between the documents to ensure the ARPANSA IMS met all of the applicable requirements. The ARPANSA IMS is improving the business efficiency and customer service outcomes. It is allowing faster access to the day to day processes, allows for better process mapping, tracking of continual improvement programmes across the agency, sharing of lessons learned from across the agency. This greater sharing with all other areas of ARPANSA allows work groups to learn from other areas concerns and look out for similar issues within their sections. The IMS is validated against ISO 9001 during our external ISO 17025 certification audits. ISO 17025 has a requirement to either be ISO 9001 certified or meet the requirement of, which are contained within ISO 17025. ARPANSA is ensuring that we meet the needs of ISO 17020, by our internal audit regime. The RSB QMS has been replaced by the ARPANSA IMS
6	Belarus	Article 10	p. 28	Could you, please, describe how and the extent to which, the regulatory body ensures the achievement of a common understanding, within its organisation, of the key aspects of safety culture? How is it evaluated?	ARPANSA has published the Holistic Safety Guidelines, which outline key principles of holistic safety/safety culture (see https://www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/holistic-safety/guidelines). The objective of the Guidelines is to provide guidance on key technological, individual or human, and organisational aspects that are necessary to create and maintain optimal safety. The Guidelines may be used to assess and monitor compliance with the Act and Regulations. The guidelines are also applied to ARPANSA staff to ensure a common understanding of key aspects of safety culture/holistic safety. The Holistic Safety principles have developed from the analysis and lessons learned from incidents, accidents, and real-life events. ARPANSA has taken these principles, and international best practice into account to produce the Holistic Safety Guidelines. ARPANSA has also rolled out a custom safety culture maturity model and used it to conduct a study of its safety culture. The model draws on the Nuclear Energy Agency's publication “The Safety Culture of an Effective Nuclear Regulatory Body” and involves the collection of data through surveys, focus groups, interviews, workplace observations and document reviews. The model was rolled out on a trial basis to the Regulatory Services branch in 2019 (see link to report on https://www.arpansa.gov.au/regulation-and-licensing/regulation/regulatory-integrity/safety-culture-assessment). Having been found appropriate for an organisation like ARPANSA, it has now also been rolled out to the rest of ARPANSA (the report for this is currently being reviewed and an action plan developed). An action plan has been published for the Regulatory Services Branch and is being progressed

7	Czech Republic	Article 8	Page 22/Section 8.6 and 8.9	"8.6. ARPANSA has developed a Workforce Plan (2017–2021) that notes the identification, development and maintenance of competency requirements. In addition, in 2017, ARPANSA undertook a comprehensive review of all positions in the organisation as part of ongoing succession planning. This included identification of vulnerable areas and priority areas for strengthening resilience of some key competencies. 8.9. ARPANSA has initiated a process to adopt ISO 17020 or equivalent arrangements for all regulatory processes. As a part of that work, ARPANSA has developed and implemented a Qualification Card system with associated defined competencies that all regulatory officers must meet before being appointed as an inspector. Competencies of each candidate are formally assessed prior to their appointment under section 62 of the Act. (Page 22)" QUESTION 1: Can you briefly describe the assessment process of the candidate? Does it include any (e.g. written) form of examination? QUESTION 2: What system of recording of Qualification Card system individual fulfillment is in use (written forms in personal file, database)? QUESTION 3: Is an inspector appointment time limited?	The qualification card is just one of a number of requirements to be appointed as an inspector by the CEO of ARPANSA. The formal assessment process of the candidate comprises short assignments, observation of performance and interview questions. Records of performance of candidates for each part of the qualification card are documented on approved forms and retained in the ARPANSA quality management system. Inspector appointment is for a 3 year time period only. Prior to reappointing an inspector, an assessment is made as to whether they have actively maintained the currency of their knowledge and skills pertinent to inspections and participated in a sufficient number of inspections per year to maintain proficiency. More information on the inspection qualification program can be found in the ARPANSA inspection manual on the website (see https://www.arpansa.gov.au/sites/default/files/arpansa-reg-ins-man-280w.pdf)
8	Czech Republic	Article 8	Page 24/Section 8.20	"8.20 ... All staff members across the agency are required to make annual declarations of interests that could potentially conflict with the performance of their duties ..." QUESTION 1: Can you briefly describe how such a declaration is organized (prescribed blank form, report?) QUESTION 2: Is it possible to list a short example of "prohibited" interests?	The conflict of interest declaration applies to all staff across ARPANSA. They make the declaration when they first commence their role, and then annually or if circumstances change. The process comprises completion of a form by each staff member which lists any relevant interests or relationships that may influence or could be seen to influence any decision they are taking or advice they are giving in relation to their position at ARPANSA. It also requires each staff member to declare relevant interests/relationships of immediate family members, who then also have to sign the form if applicable. Relevant interests that need to be declared include beneficial interests (paid contracting work or funding received) pecuniary interests (financial shareholdings for example) professional interests and any other personal relationships or activities engaged in that may be perceived to influence performance of duty.

9	Czech Republic	Article 16	Page 39/Section 16.7	Do you also perform secret staff exercises on the OPAL reactor, or do you practice only 3 types of exercises, as outlined in the report?	ANSTO also undertakes security exercises and drills involving the OPAL reactor as required by the relevant competent authorities and agencies. In addition to the exercises referred to in the National Report, ANSTO also undertakes regular internal emergency exercises and that the OPAL operations shift personnel also complete desktop emergency exercises on a monthly basis.
10	Czech Republic	Article 17	Page 42	Are any protective measures realized for operating research reactor, the Open Pool Australian Light-Water Reactor (OPAL), relating to extreme temperatures and wildfires?	In extreme high ambient temperatures, ANSTO has previously found it necessary to reduce the OPAL operating power due to limitations on the ability of the cooling towers to eject heat to the environment. However, ANSTO recently introduced some changes to the safety case (as contained in the SAR) that should allow more flexibility in future. In relation to bushfires, the most recent bushfire that approached the Lucas Heights site was in April 2018. At that time, both OPAL and the associated radiopharmaceutical production facilities continued to operate normally. Protective measures during this incident included onsite fire monitoring patrols and the closure of the site to non-essential staff, the latter primarily being to facilitate the operations of the offsite emergency responders by minimising traffic on the local roads.
11	Spain	Article 16	Pag. 39	Could you explain if there are automatic radiological networks around the two mentioned installation? Does these radiological network have any role in relation to trigger an emergency situation? Are there on-site and off-site emergency plans in relation to the above two nuclear installations?	Both ARPANSA and ANSTO have automated gamma-rate detectors installed on the ANSTO/ANM site at Lucas Heights. ARPANSA's detectors feed data to a Geographic Information System (GIS), and data obtained is intended for use to trigger ARPANSA's emergency response procedures. On-site emergency plans are maintained by the operator (ANSTO). These have been reviewed by the regulator (ARPANSA). Off-site emergency plans are captured under the Lucas Heights Emergency Subplan. This Sub Plan details the coordination arrangements that will apply to Lucas Heights geographic area only, assuming an Emergency Preparedness Category II event under the IAEA Safety Standards. It would only be activated for an emergency at ANSTO that is nuclear or radiological related, and has therefore never been activated. Lucas Heights Emergency Sub Plan (2019) -can be found on the following link: https://www.emergency.nsw.gov.au/Pages/publications/plans/sub-plans/lucas-heights-emergency-sub-plan.aspx
12	Spain	Article 16	Pag. 40	Could you describe the codes used to model the airbone radiactive plumes? / it is said that during the Fukushima nuclear emergency, ARPANSA provided continuous technical advice to the Australian Government. Using weather prediction data, ARPANSA modelled the movement of airborne radioactive plumes, both potential and real, on a daily basis to ensure that Australians were given adequate advice while in Japan. ARPANSA also worked with Australia's food standards regulator to assess the available information on contamination levels in water, milk and foodstuffs in Japan and to screen foodstuffs imported to Australia from Japan and made the information available publicly	Two atmospheric dispersion tools were used during the modelling of plumes in the response to the Fukushima-Daichi radiological releases. These were ARGOS (short- and medium-range) and HySplit (long-range). ARGOS is an atmospheric dispersion and decision support tool that incorporates the Rimpuff model. This is a Gaussian puff model, with weather information (wind and precipitation predictions) provided by Australia's Bureau of Meteorology. HySplit is the NOAA Air Resources Laboratory Trajectory Model. Global weather data obtained within the online version of the HySplit model were applied for long-range trajectories. ARGOS: Information on the ARGOS system and Consortium can be found at http://www.argosconsortium.org/Articles/argos.html, and https://pdc-argos.com/. The evaluation of the ARGOS system for use in Australia can be found on the ARPANSA website: ARPANSA/TR150, September 2008 - Evaluation of ARGOS for use in Australia - Marcus Grzechnik, Rick Tinker and Stephen Solomon. HySplit information can be found at https://ready.arl.noaa.gov/HYSPLIT.php

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16	Belgium	Article 9	9.5	This § talks about planned inspections. Are unplanned inspection also done ? How many, compared to planned inspection ?	Inspections are usually scheduled according to the baseline frequency which is based on calculated regulatory priority of facilities. Unscheduled inspections beyond the baseline may also be conducted. These 'augmented' inspections are likely to occur in response to specific circumstances such as an incident, accident, non-compliance or area for improvement. In such cases, targeted inspections of a defined scope will be planned, scheduled, and communicated to the licence holder. In certain circumstances, it may be necessary to conduct an unannounced inspection. Such inspections are in response to a specific situation or event. The licence holder will be notified of the inspection prior to entry. In addition, site visits supplement the inspection program but are not inspections. Generally, site visits are used by inspectors to familiarise themselves with processes, procedures or personnel or to witness operations. The information gathered is usually used to inform a decision-making process such as licence assessment request or sharing information with a licence holder. Observations and information are recorded in a Site Visit Report. This report is not provided to the licence holder or published, however observations are expected to be discussed with management/personnel during the visit where relevant. If a non-compliance is identified during a site visit an unannounced inspection may be initiated. In this situation, the inspector should announce that they are now collecting evidence on behalf of the CEO of ARPANSA to assess compliance with the Act and Regulations. In the reporting period since the last CNS Review meeting, ARPANSA has conducted 10 announced inspections and 48 site visits on the OPAL reactor. No augmented or unannounced inspections have been considered necessary. For more information on the inspection process see the link https://www.arpansa.gov.au/sites/default/files/arpansa-reg-ins-man-280w.pdf to the ARPANSA Inspection manual.
17	Belgium	Article 13	13.2	What are the main differences between the ISO17020:2012 QMS-system, which was identified during the 7th RM as a Good Performance, and the IMS-system that is under development?	The ARPANSA Integrated Management System (IMS) is aligned to meet the requirements of ISO 17020:2012. The current version of the ARPANSA IMS is certified to ISO 17025:2017 (general requirements for the competence of testing and calibration laboratories), both ISO 17020 and ISO 17025 are very similar in requirements. The internal audit structure for the regulatory services branch of ARPANSA is based on our certified ISO 17025 requirements and where applicable the branch is additionally audited to the requirements of ISO 17020. As a result, the good performance that was identified previously has been improved upon and developed in to the IMS to now not only fully incorporate the requirements of ISO 17020, but a number of other codes and standards that ARPANSA is either certified to, or the IMS aligned to and internally audited against.

18	Japan	General	p5	By when will ARPANSA decide the site for NRWMF? Do you have a deadline for the site selection from the point of waste management?	The Department of Industry, Innovation and Science (a separate government department to ARPANSA), that as of 1 February 2020 is now known as Department of Industry, Science, Energy and Resources, is responsible for establishing a National Radioactive Waste Management Facility under the National Radioactive Waste Management Act 2012. (See https://www.industry.gov.au/strategies-for-the-future/managing-radioactive-waste for more information). ARPANSA is the licensing authority for the facility. The process to licence a National Radioactive Waste Management Facility (NRWMF) is described in ARPANSA's Regulatory Guide: Applying for a licence for a radioactive waste storage of disposal facility (May 2017) (the Guide) and Information for Stakeholders: Radioactive Waste Storage and Disposal Facilities (May 2017). The Guide describes the legislative framework applying to such a licence, the licensing process, the protection of people and the environment (including the need for a safety case) and outlines international best practice. The essence of the licensing decision is whether the applicant can supply a safety case that satisfies the ARPANSA CEO that the facility would not have an adverse impact on human health or the environment. The CEO is required to take into account international best practice in relation to radiation protection and nuclear safety. The CEO must also invite public submissions on the application and take any submissions into account when making a licensing decision. ARPANSA does not control the timeline for establishment of this facility.
19	Japan	Article 16	p12	Did OPAL inform external responders of the scenarios in advance?	Yes, external responders were informed of the exercise scenario in advance of the exercise being undertaken.
20	Japan	Article 8	p. 11 and 25	In response to a recommendation from the 2018 IRRS mission, ARPANSA developed and piloted a custom-built safety culture maturity model. Annual self-assessments are published on the ARPANSA website. On the questionnaire survey done to the ARPANSA staff, could you please describe what kind of questions were asked and how the answers were analyzed for ranking its maturity on a five point scale from `pathological' to `holistic'.	The survey was designed to provide information about people's perception of culture related factors such as leadership, risk, rule following, speaking up, team and divisional dynamics. Full details are found on the ARPANSA website (https://www.arpansa.gov.au/sites/default/files/safety-culture-assesment-report2019.pdf). This survey was designed in alignment with the safety culture maturity model elements and sub-elements. Respondents were asked to select a 'statement' that corresponded to a maturity level that, in their opinion, best represented how they see the safety culture within RSB for each of the sub-elements. The areas that were asked about were focussed on leadership for safety, individual responsibility and accountability, safety oversight and systemic approach, collaboration and open communication and continuous improvement. For example, questions targeted whether there was adherence to procedures, communication, workload and management support and leadership style. The most commonly selected response determined the culture score, both for the elements and sub-elements. This method was preferred over averages to more accurately highlight the discrete nature of maturity. For example, if 4 responses were at bureaucratic (2) and 10 at holistic (5) maturity level, the average would yield cooperative (4.1) despite the fact that none of the respondents selected the statement for cooperative. Instead the mode is used for the ranking, and variation is captured by including the 30th and 70th percentile scores which show the average response range. (note: For the pilot study the range was based on the standard deviation of the sample set, however on the larger data set of all responses the common convention of using the interquartile range (25-75%) was adopted as this gives a more consistent approach between sets). In this way, maturity ratings were produced for each of the five elements and twenty sub-elements based on responses provided. The Project Team took several steps to ensure the privacy and confidentiality of survey respondents. The survey was conducted as a voluntary and anonymous online survey and employees were not tracked in the process. Identifying information was not collected. The Survey Monkey platform was used to host the survey with only the Project Team members having access to the survey data. The consultant involved was bound by the code of conduct and ethical guidelines of the Australian Psychological Society and the Psychology Board of Australia. The response set to the questions were developed through consideration of the OECD NEA The Safety Culture of an Effective Nuclear Regulatory Body (2016), as well as relevant international publications such as the IAEA's 'Performing Safety Culture Self-assessments (2016)' and the associated 'Safety Culture Perception Questionnaire.

21	Japan	Article 7	p4, ii) p18, 7.7.	When will the decommissioning program be fully developed and decommissioning activities commence?	The decommissioning program for HIFAR is ultimately dependent on the design and construction of the National Radioactive Waste Management Facility (NRWMF). The yet to be finalised design of the NRWMF will determine aspects such as waste acceptance criteria, which will in turn affect how HIFAR is decommissioned. HIFAR ceased operation in 2007 and is currently under care and maintenance. Some basic characterisation work is being undertaken during this period to better understand the facility and to assist in the preparation of the decommissioning program.
22	Japan	Article 6	p15, 6.5. 2nd paragraph	Why did it take around 6-months for ARPANSA directed ANSTO to initiate an independent review after making Breach decision in December 2017?	On 29 June 2018, the CEO of ARPANSA issued the Australian Nuclear Science and Technology Organisation (ANSTO) with a direction under section 41(1A) of the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act), which was tabled in Parliament on 24 August. The direction required ANSTO to take immediate steps to initiate an independent review of its approach to occupational radiation safety of processes and operational procedures at its nuclear medicine facility, ANSTO Health (Lucas Heights, NSW), in particular those associated with quality control of molybdenum-99 (Mo-99) samples. The CEO decided to issue the direction following four separate events with safety implications at ANSTO Health in less than 10 months. The first and most significant event was the contamination event of a staff member's hands on 22 August 2017. After that event, the CEO of ARPANSA found ANSTO to be non-compliant with licence conditions and, due to its severity, tabled a report in Parliament under section 61(1) of the Act. Three further events including an event on 7 June 2018 indicated ongoing safety issues at ANSTO Health. The Direction was issued following all four events and was not just based on the event from August 2017. See the link https://www.arpansa.gov.au/news/arpansa-issues-direction-ansto for more information.
23	Japan	Article 6	p14, 6.1.	What is the feature of the `possess or control' license? what is different from the operation license and what will be exempted from?	A possess or control licence is most commonly relevant to that period of safe enclosure between the operation of a facility and its decommissioning and ultimate disposal (or deferred dismantling). However, it may also be issued to cover other circumstances including an extended period of shutdown pending a resumption of operation or periods between decommissioning phases. A possess or control licence may also be issued if the CEO reduces the authority granted by the licence under sub-section 36(2) of the Act. The objective of possess or control is to ensure that, despite not being in use, a controlled facility including any source inventory remains safe and secure. It is important that controlled apparatus is not operated and controlled material is not used or disposed of where a possess or control licence has been issued. A facility must not be operated or decommissioned under a possess or control licence. These activities require separate approvals under the Act and are therefore prohibited under a possess or control licence. For example, ARPANSA currently licences the permanently shutdown 10 MW HIFAR research reactor under a Possess or Control licence (F0184). Under this licence the operator must care and maintain the reactor including refurbishment where needed. Subject to approval, the operator may undertake activities to radiologically characterise it in preparation for decommissioning. However, the operator is not permitted to remove any radioactive components from that facility before it applies for and is issued with a decommissioning licence. The HIFAR research reactor is also subject to regular inspections to ensure that the requirements of the Possess and Control licence are met. More information is available on the ARPANSA website (see link https://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/guides/REG-LA-SUP-240X.pdf).
24	France	Article 7	§ 7.19	Could Australia clarify whether there has been any matters referred by ARPANSA to the Director of Pubic Prosecutions in the recent years?	There have been no matters referred to the Director of Public Prosecutions by ARPANSA since the establishment of the agency in 1998.

25	France	Article 7	§ 7.9	The baseline inspection program, comprising 8 inspection areas, defines the minimum level of planned inspections to evaluate performance over a “defined period”. Could Australia clarify what is this “defined period” for OPAL reactor ?	The OPAL reactor is inspected every 3-6 months. Inspection frequency is based on regulatory priority (RP) which is calculated for each facility. Facilities are assigned a RP using the methodology described in full in section 1.6 of the Inspection Manual published on the ARPANSA Website (https://www.arpansa.gov.au/sites/default/files/arpansa-reg-ins-man-280w.pdf). The methodology is based on scoring the hazard and control of the facility. These two parameters are considered suitable as they are straightforward to assess based on existing information available to the lead inspector. The RP of facilities is reviewed at least annually. In addition the RP is reviewed after an inspection, following changes to a facility, or after an accident or incident
26	France	Article 6	§ 6.5	Could Australia detail what were the main areas for improvements identified by the independent expert review performed at ANSTO Health Radiopharmaceutical Production Facility, following the worker overexposure (Level 3 INES)?	The Independent Safety Review report can be found on the link https://www.ansto.gov.au/business/products-and-services/health/independent-report-safety-of-building-23. This review has led to the identification of 85 recommendations for improvements; these recommendations are mostly directly applicable to ANSTO or ANSTO Health, but a proportion are also relevant to the regulators including ARPANSA in order to help them to further develop as a nuclear regulatory authority. An action plan has been developed by ANSTO and approved by ARPANSA and is found on the following weblink (https://www.ansto.gov.au/sites/default/files/2019-12/ANSTO_Response_to_the_Independent_Review_of_ANSTO_Health_rev4.pdf for the plan). Some of the main areas for improvement included human factors, safety assessment process review, change management and improvement to management of safety.
27	France	Article 6	§ 6.5	Could Australia elaborate on whether the independent expert review identitied any areas of improvement for the regulatory oversight of ANSTO Health Radiopharmaceutical Production Facility?	The Independent Safety Review report can be found on the link https://www.ansto.gov.au/business/products-and-services/health/independent-report-safety-of-building-23. This review has led to the identification of 85 recommendations for improvements; these recommendations are mostly directly applicable to ANSTO or ANSTO Health, but a proportion are also relevant to the regulators including ARPANSA. The review team, noted that the interface between ANSTO and its regulators, including ARPANSA, could be improved. Although it is acknowledged that evidence was presented of the interactions between ANSTO (and ANSTO Health) and the regulator at various management and operational levels, based on practices in other countries operating nuclear programmes, there is a need for more detailed procedures and guidance by both ARPANSA and ANSTO. This is possibly due to the fact that ARPANSA is, in itself, a relatively small organisation. For example, the interfaces at different levels, from executive level down to inspector to facility level, should be formalised and a programme of such interface meetings put in place. This aids the communication and exchange process between regulators and operators and allows the appropriate fora, whereby issues at all levels may be discussed and resolved. Also, the interviews with many of the ANSTO Health staff indicated that a significant proportion did not fully understand the nuclear regulations and the associated requirements. Another issue raised by the review team was that the status of the facility assets (in particular Building 23), should be given a much higher focus by ARPANSA as potentially having a significant effect on nuclear safety. An action plan has been developed by ANSTO and approved by ARPANSA which includes some joint actions for improvement. It is also worth noting that several recommendations from the independent safety review have already been actioned such as the establishment of the ANSTO-ARPANSA Liaison Forum where the senior management of both organisations meet at 6 monthly intervals to discuss strategic issues. See link on https://www.ansto.gov.au/sites/default/files/2019-12/ANSTO_Response_to_the_Independent_Review_of_ANSTO_Health_rev4.pdf for the plan.

28	France	Article 6	§ 6.4	Should OPAL reactor be temporarily shutdown, for example due to a major safety issue, would there be other facilities able to produce radiopharmaceuticals and radioisotopes necessary for medical treatments? Could Australia elaborate on whether ARPANSA would be subject to stakeholder pressure to avoid having the reactor shutting down?	If OPAL was shut down, there is no domestic capability to produce radiopharmaceuticals and radioisotopes. These would need to be imported. If a decision was made by the CEO of ARPANSA to shut down the reactor, this could be appealed to the minister (within 28 days of the decision) and the minister may confirm, vary or set aside the decision (if no decision within 60 days, the decision is confirmed). The Minister may also direct the CEO of ARPANSA with respect to the performance of the CEO or the exercise of the CEO's powers, and the CEO must follow such directions. The Minister can only issue a direction if the Minister is satisfied it is in the public interest to do so. Further, the Minister must table the decision in Parliament. Therefore, it is possible that ARPANSA could come under pressure from the Minister to reverse any decision to shut down the reactor. However, this has never occurred.
29	France	Article 14	§ 14.13	The next PSSR of OPAL is required to be submitted in 2021 and a detailed plan for this PSSR was submitted to ARPANSA for approval in May 2019. Could Australia clarify whether there is any major technical areas where in-depth investigations will be performed?	The OPAL PSSR will be conducted to a plan that has been reviewed and approved by ARPANSA. This plan has been prepared in accordance with the joint guidance provided by ARPANSA and the Australian Safeguards and Non-Proliferation Office for the PSSR of OPAL. The Joint Regulatory Guide aligns with the safety factors described in IAEA SSG-25, with the exception of the hazard analysis and inclusion of a factor on utilisation. ANSTO will address all safety and security factors outlined in the Regulatory Guide using a graded approach and the application of engineering judgement as appropriate for a research reactor consistent with this Guide. The actual condition of SSCs important to safety, analysis of operating experience and the organisation, management system and safety culture will be key focus areas. The security review will encompass physical protection measures, security management and experience. The review will consider interfaces between safety and security to determine whether potential conflicts are adequately managed and to identify areas where safety and security can be enhanced by an integrated approach.
30	France	Article 14	§ 14.6	The EU countries have performed a topical peer review on ageing management which included nuclear power plants and some research reactors One of its conclusion is that "The review did not identify any major deficiencies in European approaches to regulate and implement Ageing Management Programmes at Nuclear Power Plants. However, this is not the situation for Research Reactors. Ageing Management Programmes are neither regulated nor implemented as systematically and comprehensively, and therefore require further attention from both regulators and licensees.". Could Australia elaborate on whether such conclusion would be also relevant in Australia? Could Australia detail what are the main provisions related to ageing management at OPAL Reactor and what reviews have been performed by ARPANSA..	ANSTO OPAL is implementing an Asset Management approach based on the requirements and guidance of ISO 55001 (although at this time, no certification is intended). The Asset Management approach is considered to bound a simple Ageing Management approach since the focus is not only on the safety of the facility as it ages but also its continued operability and availability. ARPANSA conducts routine inspections on the OPAL reactor, one of which covers the performance objective criteria of Inspection Testing and Maintenance which addresses the Asset Management program. In addition, OPAL is required to perform Periodic Safety and Security Reviews (PSSR) (the next one is due to be submitted in 2021. The PSSR will be conducted using the ARPANSA Periodic safety and security review of facilities guide REG-COM-SUP-2701 (see linkhttps://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/guides/REG-COM-SUP-270I.pdf). This guide was written based on International Best Practice, namely the IAEA Safety Guide Periodic Safety Review of Nuclear Power Plants SSG-25 [1] and draft of the IAEA Safety Report Periodic Safety Review for Research Reactors. Safety Factor 4 of the PSSR requires whether an effective ageing management program is in place to ensure that all required safety functions will be delivered on demand for the design lifetime of the facility or at least until the next PSSR, and to determine whether the ageing process affecting SSCs important to safety is effectively managed. A PSR was previously conducted by OPAL and approved by ARPANSA in 2014 which also reviewed in detail this Safety Factor.

31	France	Article 13	§ 13.1 8.12	ARPANSA has a Quality Management System (QMS) to develop and maintain policies, procedures, forms and guides of a regulatory nature. The QMS meets the requirements of AS/NZ ISO 9001 standard and ARPANSA is planning to achieve certification to AS/NZ ISO 9001. The QMS is being integrated with the Integrated Management System (IMS) under development across the agency. Could Australia clarify what are the interfaces/relationship between the QMS and IMS? Could Australia clarify what provisions are implemented to ensure the QMS is consistent with IAEA GSR Part 2 and associated Safety Guides?	The existing Quality management system (QMS) was clause- compared, gap- analysed to the desired standards and to the certified standard ISO17025. From there, the QMS sections that were compatible with the IMS were then directly inserted into the new IMS. Where the gaps were/have been identified in the (outgoing) QMS, the IMS was written to cover these gaps with the supporting new processes developed to meet the missing requirements. ISO 17025 is the main driver of the new IMS as this is our certified standard (certified since 2002). IAEA GSR Parts 2 and 3, SSG-50, and NG-T-1.1 are some of the IAEA documents with which ARPANSA's IMS aligns. In addition to these IAEA documents, the IMS is also aligned with a number of ARPANSA's published codes and standards.
32	Belgium	General	f) International Peer Review Missions	A reporting on the results of the IRRS mission and the status of its action plan would be welcome during the country presentation.	Australia thanks Belgium for this comment and will include the results of the IRRS mission and status of the action plan in the National Presentation as suggested.
33	France	Article 12	§ 12.6	There has been a number of nuclear safety related events reported for OPAL, but none have been identified as significant by ARPANSA. Although not so significant on an individual basis, could Australia clarify whether these events show trends or result from similar causes?	There are actually very few nuclear safety incidents raised at OPAL and the only common feature of some of these incidents relates to shortcomings in the original design and/or verification of construction of the OPAL reactor. All incidents are managed through the ANSTO GRC event management system to ensure they are addressed.
34	France	Article 11	§ 11.3	Could Australia detail the number of inspectors that are regularly performing inspections at OPAL in addition to the lead inspector.	All inspections require two inspectors as a minimum. In this respect, since the last CNS meeting, there have been six different inspectors performing inspections at OPAL as well as the current lead inspector. This is a key part of knowledge sharing, succession planning and ensuring the correct expertise is applied to the different areas of inspection. ARPANSA also practices inspector rotation. Lead inspectors should be rotated periodically to: improve organisational resilience, contribute to succession planning, improve teamwork and cooperation, avoid regulatory capture and enhance inspector experience and engagement. Details of inspector management are available on the ARPANSA website http://isaac.arpansa.local/OurBusinessUnits/RegulatoryServices/continuous/Pages/inspection.aspx
35	France	Article 10	§ 10.1	Could Australia clarify why ARPANSA was involved in the development of ANSTO safety performance indicators ?	When issuing the OPAL Licence to Operate in 2006, ARPANSA included a licence condition requiring: "The Licence Holder must maintain a set of safety performance indicators to be agreed by the CEO of ARPANSA.". ARPANSA was not involved in the development of these indicators directly but approved the final set in order to ensure that they were in line with key international best practice such as IAEA-TECDOC-1141, applying of course a graded approach for research reactors. Full information on why ARPANSA required the development of these SPIs in line with International Best Practice can be found on the following link for the Statement of Reasons for Licensing the OPAL Reactor: https://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/opal/op/oplic_reasons.pdf

36	France	Article 8	§ 8.31	The safety culture assessment identified some areas of improvements. One of them is to develop strategies for enhancing individual responsibility and accountability. Could Australia elaborate on the basis/context of this recommendation , as well as current ideas to address it?	This recommendation was from the analysis of the results related to the 'Individual responsibility and accountability' element. This element describes individual commitment and ownership around their role and the standards they meet to support safety and regulatory outcomes. The overall safety culture maturity result for this element was at an Individual level. Personal accountability and commitment to a high standard for behaviours exhibited and performance is important in a healthy safety culture. Support and reinforcement of this responsibility and accountability should come from leaders, and the management systems in place. Findings indicate that there is some room for improvement in building a shared view of collective responsibility, and in how the organisation supports 'speaking-up' behaviour. One of the recommendations for this area was as follows: Strategies for enhancing 'Individual Responsibility & Accountability' rating should be investigated in relation to Procedural adherence and the management system. For instance, it is suggested that feedback is sought from employees about their views and responsibilities in relation to the demands of the management system. The core objective in such an activity would be to examine the interface between employees and the management system that impacts on efficiency and effectiveness in meeting key outcomes. Additional context: The report identified that people did not always follow the management system because they 'knew what they were doing'. The report did not identify why, but considered that this may be that people felt that following management systems did not always lead to the best outcomes - for example using an alternative approach that achieves the same key outcomes more efficiently. There are likely a number of factors that lead to this perception. These may include a lack of clear roles in the procedure, effective change management to update procedures, adequate resourcing, seeing the value of all steps in a process, and the management oversight of procedural adherence. The current action plan and safety culture perception plan with full details are on the ARPANSA website (see linkhttps://www.arpansa.gov.au/regulation-and-licensing/regulation/regulatory-integrity/safety-culture-assessment). The plan to address it comprises the development and introduction of a system of procedural adherence management (including reviews/audits where applicable), which ensure that deviations are accounted for and documented, to ensure positive outcomes and effective procedures. The primary purpose of this is to understand the reasons for any non-conformance, to drive continuous improvement in our systems and where necessary to reinforce accountabilities. The management system should record the consultation on procedure development and revision. The expected outcome of this recommendation is that staff follow clear procedures that are appropriate to outcomes. The measure of success will be high level of procedural adherence to procedures that reflect effective processes and the sustaining outcomes will be periodic review of procedural adherence. This action is expected to be developed, implemented and reviewed for effectiveness by 2021 as per the action plan.

37	France	Article 8	§ 8.26 8.27	ARPANSA, in conjunction with an external consultant in safety culture and organisational psychology, developed and piloted a custom-built safety culture maturity model in the RSB. The model ranks performance in five elements each with four sub-elements. Maturity is ranked on a five point scale from 'pathological' to 'holistic'. Could Australia provide addition details on this model?	The model was based on the OECD Nuclear Energy Agency (NEA) publication 'Safety Culture of an Effective Nuclear Regulatory Body'. The model was adapted from the 'Safety Culture Maturity Matrix' and framework developed by Bel V (2018). The model is also generally consistent with the guidance for safety culture assessment of the International Atomic Energy Agency (IAEA) Safety Standard GS-G-3.5 'The Management System for Nuclear Installations'. However, it has been modified to be more targeted at the role of the regulator rather than the operator. The maturity model was anchored to five maturity levels comprising 1) Pathological, 2) Bureaucratic,3) Individual Commitment, 4) Cooperative and 5) Holistic. While the rating levels are in order of maturity, with the more desirable states being from level 5 down to least desirable level 1, the model is not linear in that each state represents a discrete cultural aspect. As such, variance in the response should not be seen as half-way between states, but rather that some aspects/individuals may be in one state of safety culture maturity while others are in a different state. The level of maturity was assessed through the following five safety culture elements - leadership for safety, individual responsibility and accountability, safety oversight and systematic approach, collaboration and open communication, continuous improvement and self-assessment. The key source of data was from an online survey distributed to all employees within the RSB. In addition, a 'triangulation' data collection process was used which involved the gathering of data using four collection methods in total. This combination of methods ensured that available data was sourced from a variety of perspectives and places. Collation of these perspectives enabled comparison, verification and sense-making of the data. Full details of the model are now available on the ARPANSA Website (see link https://www.arpansa.gov.au/sites/default/files/safety-culture-assesment-report2019.pdf).

38	France	Article 8	§ 8.1 8.20	The CEO of ARPANSA has both regulatory and non-regulatory functions. The non-regulatory functions include providing radiation monitoring and calibration services, and undertaking research. ARPANSA Regulatory Service Branch assists the CEO to perform his regulatory functions. RSB has delegated regulatory functions for licensing, inspections, compliance management, and enforcement, and this provides some structural clarity to the regulatory function.Could Australia elaborate on how is the independence of ARPANSA regulatory functions not compromised by its non-regulatory functions as RSB is under ARPANSA CEO ?	The CEO of ARPANSA is a statutory office holder and is independent of interests that promote the introduction/utilization of nuclear and radiation technologies. The CEO is ultimately responsible for the regulatory decisions, and the regulatory staff of ARPANSA is accountable to the CEO regarding their delegated regulatory roles. However, section 15 of the Australian Radiation Protection and Nuclear Safety Act 1998 (ARPANS Act) also confers on the CEO of ARPANSA (CEO) a number of other functions. Included in these functions is performing certain activities required to be licensed under the ARPANS Act and providing some commercial services that potentially could compete with private providers for the business of other entities licensed under the ARPANS Act. In these circumstances the potential exists for certain conflicts of interest to arise or be perceived to arise and consequently subsection 15(2) of the ARPANS Act provides that the CEO must "take all reasonable steps to avoid any conflict of interest between the CEO's regulatory functions and the CEO's other functions". Conflicts of interest are likely to arise only infrequently between the CEO's regulatory functions and the CEO's other functions. Below, two examples of theoretical conflicts between regulatory and other functions are examined: 1.where the exercise of the regulatory power could be perceived to financially advantage ARPANSA, because it would produce revenue – for instance the imposition of a licence condition which incidentally requires the licensee to utilise a commercial service offered by ARPANSA; 2.where ARPANSA is effectively required to regulate itself – for example, where ARPANSA owns equipment which is required to be licensed under the ARPANS Act. Conflicts of interest require management if they are 'material' – that is where a reasonable disinterested person would think the two functions could conceivably conflict or appear to conflict. As explained in the Explanatory Memorandum to the ARPANS Act, the fact that any such licensing decision is subject to review by the Minister and by the Administrative Appeals Tribunal is considered sufficient to address any such perceived conflict of interests. In addition, to the review mechanisms available to persons affected by such a decision, ARPANSA deals with this potential conflict through staff training and policies and procedures requiring decision-makers to expressly and explicitly exclude from the decision-making process any consideration of the potential benefit ARPANSA might receive because fees would become payable by the person granted the licence. The second conceivable conflict arises from the fact that ARPANSA is effectively required to regulate itself because it owns equipment that must be licensed or regulated under the ARPANS Act. To manage this conflict, ARPANSA has adopted a practice of, as necessary, securing external oversight of its self-regulation, e.g. by inviting an inspector from another jurisdiction to provide oversight of ARPANSA's self-inspections and self-licensing decisions. Both the measures outlined above are considered to constitute 'reasonable steps' to avoid conflicts of interest between the CEO's regulatory and other functions for the purposes of subsection 15(2) of the ARPANS Act. Other particular measures may be reasonable in other specific circumstances should they arise. E.g., the CEO may implement measures to ensure that ARPANSA is organised and governed in a way that ensures that the CEO's regulatory functions can be discharged effectively and with the necessary rigour and legal oversight. An explanation of the intersection between regulatory and other functions is available at the ARPANSA website (see https://www.arpansa.gov.au/regulation-and-licensing/regulation/our-regulatory-services/regulatory-intersection-other-functions).

39	France	Article 19	§ 19.17	ANSTO uses a Governance Risk and Compliance (GRC) system for incident management. The system is also used to detail the investigations and analyses related to those events. ANSTO is required to report to ARPANSA within 24 hours all events at (or potentially at) INES Level 2 and above. However, ANSTO also voluntarily sends quarterly reports to ARPANSA on all nuclear safety-related events at INES level 1. Could Australia elaborate on: How events rated INES Level 0 are addressed? The reasons for a quite long reporting timeframe (3 months) for events below INES Level 2? Who has the final word on INES Level? If it is ARPANSA, should not ARPANSA be informed as soon as a reportable event been identified?	INES level 0 and 1 events are reported to ARPANSA quarterly unless they are categorised to be 'accidents' under Section 58 of the ARPANS Regulations, the implementation of which is detailed in the ARPANSA Regulatory Guide Reporting an Accident (REG-COM-SUP-274A v4.3). This Guide is available on the ARPANSA website (see linkhttps://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/guides/OS-COM-SUP-274A.pdf) and details the criteria for what constitutes a reportable accident When an incident is registered in the ANSTO GRC, it is allocated a category depending on the type of incident it is and under the general category safety incidents, there is a sub-division nuclear safety. In practice, there are very few nuclear safety incidents raised but when they are, the default position is that an INES rating is required unless there is a justifiable reason why it should not be rated. INES ratings may also be determined for other incidents as determined by the Reactor Manager in consultation with the Chair of the reactor safety committee. INES ratings for nuclear safety incidents within OPAL are performed by Reactor Operations staff with appropriate training and experience with the INES system and approved by the OPAL Reactor Manager. Following experience with the INES rating of incidents early in OPAL's operating history, OPAL now has a formally documented process for determining and recording the INES rating of a nuclear incident consistent with the IAEA INES User Manual. ARPANSA performs its own assessment of the INES rating of the event, based on information provided by, or requested from, ANSTO, and supplemented by ARPANSA's own investigations as necessary. ARPANSA reports the provisional and final rating of the event to the INES database. So far, there has been no instance of discrepancy between ANSTO's and ARPANSA's assessment
40	France	Article 16	Box on Fukushima	ANSTO has undertaken a formal safety reassessment in accordance with IAEA Safety Report Series No. 80 Safety Reassessment for Research Reactors in the light of the accident at the Fukushima Daiichi Nuclear Power Plant. A number of recommendations were made, none of which require immediate corrective action but all of which are opportunities for improvement. ANSTO has also reviewed its emergency operating instructions to ensure they cover the additional fault scenarios identified. At the time of writing this report the majority of actions were complete. Could Australia elaborate on what are the main actions not yet completed and what are the expected completion date?	A number of the actions identified in the safety reassessment have subsequently been absorbed into ANSTO's plan for addressing and incorporating Design Extension Conditions (DECs) into the SAR. A regulatory licence condition is in place that requires the completion of this DEC Action Plan and the associated submission of a revised SAR by December 2020. In most cases, these actions relate to additional analysis for identified DECs (e.g. the plant response to an extended loss of all electrical power, analysis of the simultaneous seizure of both operating primary pumps) and a demonstration that appropriate means of mitigation or accident management are in place (e.g. ensuring the ability to refill the reactor pool by multiple independent means under extreme situations).
41	France	Article 16	§ 16.7	The OPAL reactor conducted three major emergency exercises in the last three years. All exercises involved external organisations and response teams. Could Australia detail what were the main lessons learned from these exercises?	The main lessons learned from these exercises were related to the availability of internal suitable equipment and improving communication within the organisation and to stakeholders during the course of the emergency. All lessons have been managed through the action tracking system at OPAL.

42	Germany	Article 19	p. 47	It is stated in the National Report that "ANSTO is required to report to ARPANSA within 24 hours all events at (or potentially at) INES Level 2 and above. However, ANSTO also voluntarily sends quarterly reports to ARPANSA on all nuclear safety-related events at INES level 1." Could Australia please inform whether it is intended to update the reporting regulations and include events, which are below INES level 1	INES level 0 and 1 events are required to be reported to ARPANSA quarterly unless they are categorised to be 'accidents' under Section 58 of the ARPANS Regulations, the implementation of which is detailed in the ARPANSA Regulatory Guide Reporting an Accident (REG-COM-SUP-274A v4.3). This Guide is available on the ARPANSA website (see supporting document link on https://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/guides/OS-COM-SUP-274A.pdf) and details the criteria for what constitutes a reportable accident. The criteria include any event which has the potential to be INES level 2 or above but can also include INES 0 or 1 depending on the nature of the event. Any event categorised as an 'accident' under Section 58 must be reported to ARPANSA within 24 hours
43	Belarus	Article 10	p. 28	Could you, please, clarify how does the management system of the regulatory body ensure that conflicting requirements or opinions are dealt with by adequate processes and that the regulatory decision-making process is open and transparent?	Usually these differences are resolved by discussions within a peer group or with supervisors. Occasionally an employee may express a professional opinion which differs from prevailing staff opinions, or management decisions and which is not resolved through normal processes. Where a consensus is not achievable, a procedure is in place for managing differing professional opinions. This process involves the preparation of a submission to the Chief Regulatory Officer, or other Branch Head. This is then passed to an independent reviewer to assess the technical issues. A report is prepared by the reviewer and considered by the Chief Regulatory Officer. This decision may be appealed to the CEO of ARPANSA. The Australian Radiation Protection and Nuclear Safety Regulations provide that if a facility licence application relates to a nuclear installation, the CEO of ARPANSA must invite people and bodies to make submissions about the application, provide a period for making submissions, and provide procedures for making submissions. The RSB's regulatory processes are fully transparent including decision making. The regulatory assessment reports that form the basis for licensing decisions for nuclear installations are, for major decisions, published on ARPANSA's website and are available for public scrutiny. The CEO also publishes a 'statement of reasons' for all licence decisions in relation to nuclear installations. Inspection reports and findings of breach are also published on the web. The Act makes it mandatory for the CEO to report to Parliament quarterly and annually on operations of the CEO, ARPANSA and the advisory bodies. Such reports include findings of breach. The CEO can also at any time table a report in Parliament on any matter that relates to the CEO's functions
44	Belarus	Article 10	p. 28	Could you, please, explain how it is ensured that actions aimed at enhancing stakeholder satisfaction would not compromise regulatory functions and responsibilities for safety?	Actions aimed at enhancing stakeholder satisfaction are in line with the Australian Government's requirement for all Commonwealth regulators to act under the Regulator Performance Framework. See link https://www.pmc.gov.au/sites/default/files/publications/Regulator_Performance_Framework.pdf for full details. The Government released its Regulator Performance Framework as a commitment to reduce the cost of unnecessary or inefficient regulation imposed on licence holders. The Framework has been developed following consultation with a range of stakeholders and consists of six outcomes-based key performance indicators covering reducing regulatory burden, communications, risk-based and proportionate approaches, efficient and coordinated monitoring, transparency, and continuous improvement. None of these areas are considered to compromise the function of ARPANSA or its responsibility for safety. All are focussed on improving regulatory performance and reducing red tape.

45	United States of America	Article 8	page 25, 28	In response to the 2018 IRRS mission, ARPANSA developed and piloted a custom-built safety culture maturity model within the Regulatory Services Branch. This led to two recommendations, four areas of improvement and one good practice. The report indicates that an action plan is being developed to address these areas for improvement and recommendations. The report also states that a complete agency roll-out of the safety culture assessment was planned for the second half of 2019. Please discuss the status of the action plan and agency-wide deployment of the safety culture assessment.	The action plan for the Regulatory Services Branch (RSB) has now been developed and published on the ARPANSA Website (see link https://www.arpansa.gov.au/regulation-and-licensing/regulation/regulatory-integrity/safety-culture-assessment). The Objectives and actions have been identified for different findings and a timeframe set for completion. As the implementation progresses most actions have a review step, prior to the evaluation step, this allows for adjustments to be made prior to the evaluation of the measure. The highest priority was assigned to the finding regarding 'Individual Responsibility & Accountability', which relates to procedural adherence and the management system. Actions to address this finding include developing and introducing a system of procedural adherence management (including reviews/audits where applicable). The primary purpose of this is to understand the reasons behind any non-conformance, to drive continuous improvement in our systems and, where necessary, to reinforce accountabilities. The status of the agency wide deployment is that the assessment has been completed and the draft report and findings are as of December 2019 under review, with an action plan expected to be developed in 2020.
46	United States of America	Article 19	page 5	The 6th review meeting identified engagement with the wider Australian community over planned waste facilities as a challenge. Since that meeting, ARPANSA has undertaken a stakeholder engagement project with significant outreach activities beyond those required by regulation. The US commends Australia on this expanded outreach program and encourages other countries to go consider this practice. This could be considered a good performance.	Australia thanks the USA for this comment
47	Belarus	Article 8	p. 21	Could you, please, provide information about the structure of national regulatory authority?	ARPANSA comprises three service branches. The service branches comprise the Regulatory Services Branch, the Medical Radiation Services Branch and the Radiation Health Services Branch. Enabling support is provided by the Office of the CEO, the Corporate Office and the Office of the General Counsel. The ARPANS Act also establishes three advisory bodies to the CEO of ARPANSA. These bodies are the Radiation Health and Safety Advisory Council (members appointed by the Minister), the Radiation Health Committee and the Nuclear Safety Committee (the two latter with members appointed by the CEO of ARPANSA). The ARPANS Act specifies the categories of membership for the Council and Committees. Full details of the structure are found on this link: https://www.arpansa.gov.au/about-us/organisational-structure

48	United States of America	General	page 10	The IRRS mission in 2018 was a multi-jurisdictional review that included the self-governing jurisdictions in Australia. The mission identified 23 recommendations and 12 suggestions for improvements addressed to various Australian governments and regulatory bodies. A follow-up mission is planned for 2021-2022. (1) Please discuss the status of implementing the recommendations and suggestions from the 2018 IRRS mission. (2) Please clarify how ARPANSA is coordinating the implementation of these resolutions across the various governments and regulatory bodies that participated in the mission and received recommendations and suggestions for improvement.	Australia is progressing well on implementing the recommendations and suggestions from the 2018 IRRS mission. Those findings directed to ARPANSA are the most advanced in their implementation. This is because ARPANSA is the single authority on developing responses. Australia developed a national action plan to provide strategic guidance and progress on implementation of the findings of the 2018 IRRS mission. The action plan contains a reporting matrix that separates findings and groups them by responsible bodies. ARPANSA coordinates input from multiple agencies and governments to populate progress reports for the action plan. Once the action plan has been agreed by all governments, it will be published publicly on ARPANSA's website and updated as progress occurs. For multi-jurisdictional findings, ARPANSA does not have sole responsibility for implementing them. The responsible body is the Environmental Health Standing Committee. For details about this committee, please see - https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-environ-enhealth-committee.htm This committee includes senior Health representatives from each State and Territory and the Federal government. The members have established a radiation protection expert reference panel to provide technical input into implementation. Reporting on progress against the IRRS findings is put into the action plan every six months. Findings addressed to the Australian Government have been allocated to the Commonwealth Department of Industry, Innovation and Science (note: as of 1 February 2020 DIIS is now known as Department of Industry, Science, Energy and Resources). They have policy lead on the radioactive waste management facility and decommissioning. For findings addressed to ARPANSA, ARPANSA is able to directly provide input into the action plan. All findings addressed to ARPANSA have commenced implementation. Most if not all should be complete or be able to be closed on the basis of progress and confidence by the follow up IRRS mission planned for 2022.
49	Netherlands	Article 8	p.21, clause 8.1	Have any attempts been made to retain knowledge of the leaving staff? Are such attempts part of the new Workforce plan? To what extend is your QMS suited to minimize unnecessarily large knowledge drains?	The ARPANSA Workforce Plan 2017 - 2021 sets out how the agency can best place the workforce's capability, performance and productivity to enable achievement of ARPANSA's Strategic Objectives, building on current knowledge and preparing for future challenges This includes an initiative to ensure critical knowledge is not lost, ensuring knowledge sharing becomes common practice and ensuring it is integrated into the delivery of services and implementation of projects. The Plan outlines what the future workforce is intended to look like - in terms of staff and managers. The ARPANSA Quality Management System is in line with ISO9001 quality standard to facilitate this retention of records and knowledge.
50	Netherlands	Article 8	p.23, clause 8.15, 4th bullet	Clause 8.15 reads: "to advice at the CEO's request...". Is the RHS Advisory Council not allowed to provide unsollicited advise in these matters? If not, why?	The Radiation Health and Safety Advisory Council has the following functions: identify emerging issues; examine matters of major concern to the community; consider the adoption of recommendations, policies, codes and standards; and advise and report to the CEO at the CEO's request or as Council considers appropriate. Therefore, the RHSAC is able to provide unsolicited advice in any of these areas if it feels this is justified. See link https://www.arpansa.gov.au/about-us/advisory-council-and-committees/roles-and-expectations-advisory-committees for more information.

51	Netherlands	Article 14	p.34, 14.2, SAR	It is stated that a probabilistic assessment may supplement the SAR. Are there plans to make the probabilistic assessments compulsory? If so, what levels of PSA would you consider (PSA Level 1, 2, 3)?	At the time of the licensing of OPAL, ANSTO decided that the preparation and submission of a PSA would be appropriate to demonstrate compliance with ARPANSA's safety limits and objectives criteria as identified in their Regulatory Assessment Principles. As such, a Level 1 PSA with selected Level 3 consequence assessments was performed and delivered as a Contract Deliverable. A summary of this PSA is contained in Chapter 16 of the OPAL Safety Analysis Report. The ARPANSA CEO can ask for any information, such as a PSA, to be provided with licence applications under the Act and Regulations.
52	Netherlands	Article 11	p.30, 11.4, HR	Being halfway in your current Workforce Plan, could you elaborate on the relation between the Cert.IV in GI qualification and employee turnover? In other words: is it easier to obtain/train new staff who already have had their qualification elsewhere, or is there increased staff turnover since this qualification is valid elsewhere in government service also?	There is no relationship between the Cert IV in Government Investigations qualification and employee turnover. The turnover usually experienced at the ARPANSA Regulatory Services Branch is due to retirement and natural attrition
53	Netherlands	Article 8	p.25, saf culture, clause 8.27	In 8.26 a safety culture maturity model is mentioned. In 8.27 its basis is mentioned (OECD/NEA publication). This model seems to work quite well for relatively small organisations. Is the ARPANSA model also for consideration to be applied to ANSTO/OPAL?	In consultation with ARPANSA, ANSTO has applied the International Atomic Energy Agency (IAEA) safety culture perception questionnaire across selected parts of ANSTO, facilitated by third party service provider with no previous connections to either ANSTO or ARPANSA. The content of the questionnaire was developed in co-ordination with ARPANSA and used the five IAEA characteristics to aid in the understanding of the safety climate at the facilities chosen (including OPAL). The survey results were presented to ARPANSA in December 2019 and analysis is ongoing at present. In addition, the survey results from within Reactor Operations is to be used as an input into the OPAL self-assessment of safety culture that is to be performed within the scope of the OPAL PSSR, using IAEA Safety Reports Series No.83: Performing Safety Culture Self Assessments as a guide
54	Portugal	Article 7	2(ii)	Could you please share what are the expected challenges (if any), from ARPANSA's perspective, regarding the licensing for the decommissioning phase of HIFAR?	The decommissioning program for HIFAR is ultimately dependent on the design and construction of the National Radioactive Waste Management Facility (NRWMF). The yet to be finalised design of the NRWMF will determine aspects such as waste acceptance criteria, which will in turn affect how HIFAR is decommissioned. HIFAR ceased operation in 2007 and is currently under care and maintenance. Some basic characterisation work is being undertaken during this period to better understand the facility and to assist in the preparation of the decommissioning program. ARPANSA does not anticipate any major challenges once the NRWMF is established

55	Japan	Article 6	p. 10	It is written that “One safety significant incident, rated INES level 3, occurred at the ANSTO Health Radiopharmaceutical Facility in August 2017." Could you please explain what the major root causes were and what kind of measures were taken? Are there any root causes that are relevant to safety culture aspects?	The event occurred in Building 23 of the ANSTO Health facility during a routine quality control procedure and resulted in contamination of the hands of a quality control (QC) analyst. The event involved the manual handling of a vial containing a high activity solution of Mo99 (approximately 4.5GBq) in a volume of less than 0.6ml. The analyst, according to routine procedures, attempted to de-cap a crimped seal of the vial containing 4.5GBq, during which the vial was accidently dropped within the fume cupboard and splashed onto the gloves of the analyst. The analyst was wearing two pairs of gloves and found both pairs to be contaminated. In addition, the analyst then self-monitored their hands and discovered that both also had radioactive contamination. A radiation oncologist treating the QC analyst estimated an exposure of 20Gy or more to parts of the skin, which has subsequently been corroborated by modelling. This dose is in excess of the statutory annual extremity dose limit of 500 mSv. The major root causes included human factors and safety culture aspects. Examples of the major root causes are the design of the tools used to complete the task and the manual nature of the task which handles high specific activity Mo99. Contributory causes were found to be the fact the operation had been rated as a 'High' risk but allowed to continue without further mitigations implemented. 24 actions (short term and long term) were immediately developed including improvement to management of risks, re-training of staff, reduction of the amount of activity in QC samples, redesign of tools used for the task and review of automation for sampling in the future. The Independent Review which was conducted as a result of a Direction issued by the ARPANSA CEO also resulted in the development of an action plan by ANSTO (see link https://archive.ansto.gov.au//cs/groups/corporate/documents/document/mdaw/mdg5/~edisp/acs191517.pdf for more information). ARPANSA is monitoring the implementation of these actions.