



Responses to Questions Raised from Peer Review of Canada's Fifth National Report for the Convention on Nuclear Safety

Fifth Review Meeting
April 2011



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du Canada

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of Canada

Canada

Responses to Questions Raised from Peer Review of Canada's Fifth National Report for the Convention on Nuclear Safety Report

© Minister of Public Works and Government Services Canada 2011
Catalogue number CC172-27/2011E-PDF
ISBN 978-1-100-18945-1

Published by the Canadian Nuclear Safety Commission
CNSC Catalogue number INFO-0819

This document is to accompany the Canadian National Report for the Convention on Nuclear Safety – Fifth Report.

Catalogue number CC172-18/2010E-PDF
ISBN 978-1-100-16813-5
CNSC Catalogue number INFO-0805

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Responses to Questions Raised from Peer Review of Canada's Fifth National Report for the Convention on Nuclear Safety

Fifth Review Meeting

April 2011

This document supplements the Canadian National Report for the Fifth Review Meeting of the Convention on Nuclear Safety. By offering additional and detailed information in response to 113 specific questions received from 15 Contracting Parties, the document demonstrates how Canada has implemented its obligations under the Convention on Nuclear Safety. This document is produced by the Canadian Nuclear Safety Commission on behalf of Canada. Contributions to the document were made by representatives from Ontario Power Generation, Bruce Power, New Brunswick Power Nuclear, Hydro-Québec, Natural Resources Canada, Foreign Affairs and International Trade Canada and Atomic Energy of Canada Limited.

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GENERAL COMMENTS					
1	Ireland	General	N/A	Ireland would like to thank Canada for preparing a comprehensive national report on the implementation of its obligations under the CNS.	Thank you for the comment.
2	Korea, Republic of	General	Page 9	It is stated that calandria tube installation began at Point Lepreau as a part of refurbishment and Gentilly-2 also plans the refurbishment. Reportedly, many failures in the tests after new calandria tubes installation work occurred in your country. Does CNSC review and approve the calandria tubes installation procedure before the work begins? Or does CNSC regard it acceptable if the calandria tubes pass the tests regardless of the calandria tube installation methods?	<p>The CNSC reviewed the Point Lepreau replacement fuel channel design description and design requirements documents very early in the project before the work began. These documents included high level installation, test and acceptance criteria for the calandria tubes. The CNSC also reviewed the calandria vessel pressure test procedures, which included the calandria tube rolled joint installation and leak testing procedures.</p> <p>The detailed inspection and test plan for the calandria tube installation were reviewed and approved by the Authorized Nuclear Inspector (ANI). It was through the delivery of this testing that the licensee’s contractor determined that the tube installation was not adequate. A very close oversight of the installation of the calandria tubes was maintained by CNSC site officers and CNSC engineering specialists through a Type 2 inspection (audit) and meetings with the licensee on the problems with the installation, the root cause investigations, and options for resolution of the problems.</p> <p>The CNSC reviewed the installation methodology from other perspectives as well, including radiation protection.</p> <p>The CNSC is reviewing commissioning tests and is assured by the licensee, through commissioning assurance documents, that all steps of the plan are followed and that the tests are conducted at the appropriate level and delivered on the right systems.</p>

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					CNSC staff requires that calandria tubes meet the design requirements criteria. Both CNSC and ANI expectations are that any tubes that fail the acceptance criteria will need to be reworked and retested according to approved procedures.
3	Pakistan	General	Introduction-D.2 Page 6	Can Canada clarify why the Life Refurbishment of Bruce B NPPS (04 units) is not included in the life extension program of existing NPPS?	The Bruce B NPP units were not included in the life extension program for existing NPPs because Bruce Power has not yet committed to extending the life of these units. With a recent announcement in November 2010 by the Government of the Province of Ontario that the refurbishment of these units is part of its long term energy plan for the province, the likelihood of refurbishment has increased. However, there are still a number of issues that must be resolved by all parties before Bruce Power commits to the refurbishment of these units. An update of this situation will be included in the next report.
4	United Arab Emirates	General	Page 1	Report is very well presented. Appendices provide a large amount of information, and the body of the text concisely addresses the articles.	Thank you for the comment – these were two of our goals when setting out to write the report.
5	United Arab Emirates	General	Page 4	Please define NRU, in item B.3.	The National Research Universal (NRU) reactor is a versatile research and medical isotopes production facility. It is operated by Atomic Energy of Canada Limited at its facility at Chalk River, Ontario, Canada.
ARTICLE 6: EXISTING NUCLEAR INSTALLATIONS					
6	India	Article 6	Page 8	Anticipated Shutdown of Pickering B: What are the location specific reasons for influencing the decision of not to refurbish Pickering B units. Does it have any safety significance?	The decision to not refurbish the Pickering B units was driven by a number of business case factors that made this a less attractive investment versus other long-term options. Some of the considerations included: the challenges and risks posed to Ontario Power Generation in performing multiple refurbishments of reactors at both Darlington and Pickering simultaneously, the electrical output of the

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					<p>Pickering B reactor units, the economic benefits of continued operation of the units to the end of their service life, and the overall Province of Ontario electricity supply/demand situation over the potential refurbishment period.</p> <p>An Environmental Assessment was completed to assess the feasibility of refurbishing the Pickering B station. The approved Environmental Assessment concluded that the plant is safe to operate today and would continue to be safe to operate for the post-refurbishment period. This assessment was also supported by an Integrated Safety Review that was submitted to the CNSC.</p>
ARTICLE 7: LEGISLATIVE AND REGULATORY FRAMEWORK					
7	Ireland	Article 7.1	Page 24	<p>The fact that CNSC is comprised of two components is noted; Ireland would welcome more information on how the federally-appointed Commission Tribunal operates (including how members are appointed, whether membership is full-time or how frequently the Tribunal meets, what expertise/areas of interest the members cover, who the Tribunal reports to).</p>	<p>The Commission Tribunal, constituted through the <i>Nuclear Safety and Control Act</i> (usually referred to simply as the Commission) is an independent quasi-judicial administrative tribunal consisting of up to seven Commission Members appointed by the Governor in Council (the Canadian federal government). The term “quasi-judicial” refers to the fact that it is not a judicial court but that it has similar powers to compel evidence and make legally binding decisions which affect, through licensing or certification, the legal rights of a person. It is also subject to the rules or principles of natural justice (which is always the case for a traditional court).</p> <p>The Members, while appointed by the government but as members of a quasi-judicial tribunal, are independent of government, industry, Commission staff, etc. The Commission and its Members do not report to a Minister; instead, the Commission reports to Parliament through a Minister (Minister of Natural Resources Canada). They are subject to Conflict of Interests and Ethics guidelines. They</p>

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					<p>refrain from engaging into any political or partisan activity during their mandate. They hold office “during good behaviour” for up to 5-year terms (renewable), meaning that they can only be removed for cause (as opposed to being appointed “at pleasure”).</p> <p>The competency profile for Commission Members requires that they have a significant scientific, engineering and/or business background. They are not necessarily nuclear specialists, but bring a strong reputation and transferable skills to Commission proceedings. They are typically leaders in their respective field, and their achievements have been recognized by their peers. For example, the current Members of the Commission include a mining specialist, two engineers (structural and civil), a medical doctor and a business person who is also a former provincial energy minister. Their core competencies in terms of personal abilities include: leadership; an ability to listen, understand and respond in a public hearing context; empathy for participants; integrity and ethics; and a sense of equity and fairness.</p> <p>Except for the President who is a full-time Commission member, the Members of the Commission are part-time Members. They do not have offices at the Commission. They do all of their work during hearings and meetings of the Commission (9 times per year – 2 days each time – 15-20 hearings and 8-9 meetings per year). Members usually have full-time senior jobs with other organizations (universities, business, consultants, etc.), and can usually free themselves to attend hearings. They carry out their significant preparatory work (review extensive documentation from the participants) individually from their own premises the weeks prior to the proceedings.</p>

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8	Switzerland	Article 7.1	Page 24	The report says that the CNSC has a Commission Tribunal. This Commission Tribunal is a quasi-judicial administrative tribunal that establishes regulatory policy and makes independent licensing decisions as well as legally binding regulations. Please outline the requirements regarding the professional background and nuclear safety know-how of the members of this tribunal.	Refer to Serial 7 for response.
9	United Arab Emirates	Article 7.1	Page 46	It is stated that in the new licence format the licensee must obtain prior written approval from the Commission Tribunal before making any change to the licensing basis that could adversely affect the safe conduct of the licensed activities. Please describe any criteria by which the licensee and Commission staff decide which changes are safety related and trigger the requirement for prior approval. Please cite a few examples if available.	<p>Since the publication of the Canadian report to the fifth CNS review meeting, the wording of the two first “General Conditions” was changed to read as follows:</p> <p>“1. General</p> <p>1.1. The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis described in the associated LCH for the nuclear facility.</p> <p>(i) Changes to the safety and control measures described in the application and the documents needed to support that application are permitted provided that the objective of the licensing basis is met.</p> <p>(ii) Changes that are outside of the boundary conditions set by the licensing basis are not permitted without the prior written approval of the Canadian Nuclear Safety Commission (hereinafter “the Commission”).</p> <p>1.2. The licensee shall give written notification to the Commission of any changes made to the documents needed to support the licence application.”</p>

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					<p>The significant safety-related criterion for determining if any contemplated or proposed change constitutes a “safety-related change,” is whether that change affects the safety and control measures described in the documents which form part of the licensing basis. Trip setpoints are examples of such safety and control measures. If a licensee were to propose a change in setpoints such that the safety margins are increased, the change would be considered within the licensing basis envelope and would thus require notification to, not prior approval of, the Commission; the licensee would still be required to effect that change in accordance with the safety management standard (which is part of the licensing basis). On the other hand, a proposed change could result, if implemented, in a reduction in safety margins and in the NPP being taken outside the provisions of the licensing basis; in this case, prior Commission approval would be required and, in formulating their recommendation to the Commission, CNSC staff would use the CNSC risk-informed decision-making process to determine the acceptability, or not, of the incremental change in risk, if that change were implemented.</p> <p>An example of such a scenario occurred in 2009 when a licensee sought Commission approval to label a plant configuration a “guaranteed shutdown state (GSS),” that configuration being different from the accepted GSS described in station documentation (forming part of the licensing basis). Commission staff performed a risk assessment and concluded that a one-time application of such a configuration would be acceptable if certain conditions were met. A more recent example occurred when another licensee requested a reduction in redundancy, to perform battery replacements, with respect to the station’s</p>

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					DC power supplies; in this case, CNSC staff recommended against the acceptance of such a proposal.
10	United Arab Emirates	Article 7.1	Page 49	Please give details of a typical “baseline” set of inspections for a typical operating plant.	<p>The Compliance Baseline is a pre-defined 5-year schedule of compliance activities that cover all Safety Areas and Programs and which represents the minimum set of compliance activities required to verify licensee compliance with Regulatory Requirements.</p> <p>The baseline assumes there are no major licensee safety performance issues. The five year cycle is based on the current five year license renewal.</p> <p>The list of Compliance Baseline Inspections topics, derived from the CNSC’s 14 Safety and Control Areas, include:</p> <ul style="list-style-type: none"> • Management System • Human Performance Management (Staff complement, Certified Staff Training & Requalification, Training Program Evaluation) • Operating Performance (System inspections and surveillance rounds, Chemistry, Outage inspections) • Safety Analysis. • Physical Design. • Fitness for Service (Maintenance, Electrical, Pressure retaining components, Ageing Management). • Radiation Protection • Conventional Health and Safety • Environmental Protection. • Emergency Management and Fire Protection. • Waste Management • Security. • Safeguards. • Packaging and transport.

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					Refer to Question #18 for additional information and on the distinction between Type I and Type II inspections.
11	United Arab Emirates	Article 7.1	Page 36	It is noted that Canada has made progress in developing review procedures that foster a consistent and transparent approach for oversight of regulated facilities. Please outline the topics addressed by the CNSC's review procedures.	<p>The outline for procedures published so far is explained and can be found at the CNSC website using the following link:</p> <p>http://www.nuclearsafety.gc.ca/eng/licenseesapplicants/pow_erplants/newapplicants/staff_review_procedures/index.cfm</p> <p>The topics addressed were based on consideration of IAEA GS-G-4.1 the Nuclear Safety and Control Act and its regulations, the Canadian Environmental Assessment Act, and the content of Environmental Impact Statement Guidelines</p>
12	Argentina	Article 7.2.1	Article 7.2.i - Annex 7.2 (i) - Page 21	Regarding the regulatory framework for small reactors, the report says (Article 7.2.i - Annex 7.2 (i) - page 212) that the extent and rigour of the demonstration that the fundamental safety functions are fulfilled during and following a postulated initiating event vary depending on the reactor design. What are the general criteria used to decide the extent and rigour of such demonstration according the reactor design features?	<p>Regardless of the size of a reactor the CNSC uses a risk-informed review approach recognizing that additional review effort will be needed for novel approaches, and when alternative approaches to meet regulatory requirements are proposed. Particular attention is paid to the proponent's supporting research and development work to support the proposed novel or alternative approaches.</p> <p>Specific to small reactors, two new draft regulatory documents RD-367 <i>Design of Small Reactors</i> and RD-308 <i>Deterministic Safety Analysis for Small Reactors</i> allow for a graded approach to both design and safety analysis in certain areas. This is a risk-informed approach that, without compromising safety, allows safety requirements to be implemented in such a way that the level of design, analysis, and documentation are commensurate with the potential hazards posed by the facility.</p>
13	India	Article 7.2.1	7.2, Para 5, Page 27	Can you please clarify, whether CNSC has a fixed frequency for revision of the regulatory documents or the	The CNSC frequency of document revision is needs-based. Documents are reviewed, and revisions are planned and scheduled, in accordance with their priority and the availability of resources. Recent initiatives with respect to

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				revision is need based?	the management of the CNSC's regulatory framework include the establishment of a five-year review cycle for all CNSC documents where these would be withdrawn and archived, retained as is for continued use, or scheduled for revision, depending on the outcome of the review.
14	United Kingdom	Article 7.2.1	Page 26	The report states that “During the reporting period, Canada continued its efforts to enhance transparency and engage as many interested stakeholders as possible in the regulatory process”. Has the approach been to identify all stakeholder groups and, since communication is a two way process, survey them for their opinion of CNSC and the regulatory process? If so, what are the questions asked of them, and how often are surveys made, and with what size of sample? Are they carried out by an independent organisation?	Formal surveys of stakeholders have not been undertaken to date. The CNSC makes a consistent effort to identify stakeholders, including non-governmental groups, environmentalists, residents of host communities and potential host communities, provincial and municipal officials, Aboriginal groups, as well as the public at large, and provides them with the opportunity to participate in the regulatory process. For example, as part of the process for developing or amending regulatory documents or legislation, stakeholders registered with the CNSC are notified in writing of the consultation and the draft documents are posted on the CNSC Web site for public comment. Comments received are dispositioned and the draft documents adjusted accordingly. All Commission Tribunal hearings and meetings are open to the public. Tribunal hearings are announced well in advance and the agendas are posted on the CNSC Web site. Tribunal documents are available to stakeholders upon request. Any stakeholder or member of the public may request the opportunity to intervene in a Tribunal hearing either in person or in writing. As well, all Tribunal hearings and meetings are Web cast and transcripts are posted to the Web site shortly after each hearing/meeting.
15	United Arab Emirates	Article 7.2.2	Page 38	The discussion of License to prepare a site (7.2(ii)b) specifies that it is the applicant’s responsibility to demonstrate to the CNSC that the proposed site is suitable for	As discussed in Article 17, the Licence to Prepare Site application is the forum by which an applicant demonstrates site suitability for future development and the application is expected to demonstrate how the criteria in RD-346 <i>Site Evaluation for New Nuclear Power Plants</i> have been met, refer to page 144 of the National Report for details.

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				<p>further development, and that the activities encompassed by the license will not pose an unreasonable risk to health, safety, security and the environment for the site and its surrounding region. The fourth paragraph refers to CNSC document RD-346 as describing the general process for evaluating an NPP site in Canada, and the first bullet on page 39, “provides site evaluation criteria (e.g. to address the effect of the site on the environment, emergency planning, and natural and human-induced external hazards)” There is no mention of RD-346 provisions for demonstrating that the site is suitable for further development; is this in fact addressed? If so, recommend reference to RD-346 in Article 17. If not, recommend adding a reference to another implementing document, if one exists.</p>	<p>RD-346 is a ‘feed-in’ document to a new Licence Application Guide being developed by CNSC staff entitled <i>GD-368 Licence to Prepare Site for a Class I Facility: Nuclear Power Plants and Small Reactors</i>. This document goes into considerably more detail on how staff expects an applicant to demonstrate site suitability for future development. This document is anticipated to be issued for public consultation in the summer 2011.</p>
16	United Kingdom	Article 7.2.2	Page 42	<p>In order to accept the first charge of fuel on the site and store it, certain nuclear safety and radiation protection requirements have to be in</p>	<p>Should a licensee propose, prior to the granting of a <i>Licence to Operate</i>, to accept the first charge of fuel on the site and store it, an amendment to the <i>Licence to Construct</i> would be required along with a demonstration that the facility to be used for accepting and storing that fuel will meet regulatory</p>

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				<p>place. Can Canada explain how the regulation of this activity is accommodated within the Licence to operate arrangements – as the licence will not have been granted at this time?</p>	<p>requirements. This amendment would likely require Commission approval.</p> <p>In the interests of efficiency, the licensee should anticipate this activity in their initial application for the <i>Licence to Construct</i> along with details of the commissioning program needed to demonstrate that the fuel acceptance and storage facility meets requirements. The licence would then contain a suitable hold point to permit fuel delivery only after CNSC has confirmed the conditions of the hold point have been satisfied.</p>
17	United States of America	Article 7.2.2	7.2, Page 37	<p>The report states that CNSC carries out its assessment of an applicant’s supporting information with input from other federal and provincial government departments and agencies responsible for regulating health and safety, environmental protection, emergency preparedness, and transportation of dangerous goods. What is the nature of arrangements between CNSC and the other governmental bodies for the sharing of licensing information?</p>	<p>It is the CNSC’s practice to develop and maintain Memoranda of Understanding (MOU) with government bodies at the federal level having independent but related responsibilities with the CNSC in relation to nuclear projects. While the overriding objective of these MOUs is to reduce duplication of regulatory effort and streamline the regulatory process, these arrangements ensure that all obligations contained in Canadian legislation continue to be met. Consequently, information contained in an application, including protected information, may be shared between federal departments and agencies to the extent necessary to evaluate the proposed project’s compliance with legislation. Although the CNSC has several MOUs in place with other federal bodies, the CNSC is obligated to comply with any federal legislation and therefore may consult with any department or agency in assessing an application, even in the absence of an MOU, sharing any information required to complete the analysis.</p> <p>The CNSC also has working relationships with provincial and local municipal authorities, some of which may be formalized through MOUs, which set out the general parameters for cooperation.</p>

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					<p>In assessing applications, the CNSC consults with authorities at the provincial and local/municipal levels through various arrangements. For example, information may be obtained through a formal consultation, through one-on-one meetings on an ad hoc basis or through participation in regular working groups such as a local emergency operations task force.</p> <p>During the licensing or relicensing of nuclear projects, applicants are responsible for obtaining the necessary authorizations that are applicable to each level of government and must therefore provide their supporting information directly to the specific regulator.</p>
18	Ireland	Article 7.2.3	Page 47	<p>The report refers to the different types of inspections of nuclear installations. Comment: How frequently would a nuclear power plant typically be inspected under each Type I or Type II inspections and is the annual inspection programme developed ? (e.g. how are the various licensees prioritised in terms of frequency of inspection?)</p>	<p>The inspections carried out on an annual basis are based on the compliance baseline and other inspections which are “reactive” in nature.</p> <p>The Compliance Baseline is a pre-defined rolling 5-year schedule of compliance activities which cover all Safety Control Areas and Specific Areas and represents the minimum set of compliance activities required to verify licensee compliance with Regulatory Requirements. The 5 year cycle is based on the current (usual) 5-year re-licensing cycle and assumes there are no major licensee safety performance issues.</p> <p>Type I inspections review licensee programs while Type II inspections review the performance and effectiveness of these licensee programs.</p> <p>The Compliance Baseline does not include Type I inspections.</p>

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					<p>Reactive inspections (Type I or II) are conducted based on evidence of a potentially declining licensee safety performance (Type I or II) or when major changes to a licensee program are being implemented (Type I).</p> <p>The annual inspection program is generally well developed and is reviewed and updated on an ongoing basis.</p> <p>Inspections of licensees are not prioritized during normal ongoing operation however; inspection priorities may be adjusted when major activities such as outages or refurbishments are conducted.</p>
19	Switzerland	Article 7.2.4	Page 51 Page 19	<p>Concerning enforcement the country report lists a wide range of enforcement measures. However, on page 19 it is stated: “During the reporting period, the CNSC did not need to engage in formal enforcement action (requests from the Commission Tribunal, orders, licensing action, or prosecution, as described in subsection 7.2 (iv)) to resolve safety-related issues at Canadian NPPs.” This is surprising (1) for a country operating a considerable number of power reactors and (2) considering that CNSC apply a graduated enforcement where “written notices” is the less severe enforcement tool. Please explain.</p>	<p>Subsection 7.2 (iv) lists the following enforcement options in Canada:</p> <ol style="list-style-type: none"> 1) written notices 2) written warnings 3) increased regulatory scrutiny 4) requests from the Commission, or a person who is authorized by the Commission 5) orders 6) licensing action 7) prosecution <p>Page 19 describes option numbers 4) through 7) as “formal” enforcement actions, in the sense that they involve the authority of the Commission as defined in the Nuclear Safety and Control Act and its Regulations. No enforcement actions of these types were imposed on the NPP licensees during the reporting period.</p> <p>Written notices are not as “serious” as the formal enforcement options, in that they do not involve exercising the powers of the Commission tribunal (or a person authorized by the Commission), as defined in the nuclear</p>

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					<p>Safety and Control act and associated regulations. Typically, CNSC staff conveys written notices to licensee by letter to arrange for the timely resolution of safety related issues (e.g., a staff request to the licensee to develop and execute a corrective action to address a deficiency identified during a CNSC inspection). These types of written notices are, in fact, issued to all NPP licensees on an ongoing basis; many were issued during the reporting period.</p>
ARTICLE 8: REGULATORY BODY					
20	Ireland	Article 8.1	Page 67 - 69	<p>The report notes that while CNSC has been successfully maintaining and growing its employee numbers there have been some skills sets that are more challenging to fill. What skill sets are these and what steps are being taken to address any emerging gaps? How does CNSC anticipate the need for the NPP operator to recruit staff, whenever the proposed new nuclear build projects commence, will impact on its retention of staff?</p>	<p>Some senior technical positions were more challenging to fill given the limited availability of qualified personnel but the CNSC was ultimately successful in its recruiting. In some instances, the CNSC has recruited candidates with specialized education at more junior levels and has focused on training of these employees as well as providing them with various work terms within the organization.</p> <p>In the advent of resurgence in new builds, the CNSC would face increased pressures to retain staff as it would have to compete with industry for the same pool of qualified individuals.</p> <p>CNSC has been able to retain its staff over the last few years and the turnover rate is minimal. At the moment, it is focusing its HR strategies on retaining staff through concerted efforts to be an Employer of Choice.</p>
21	Korea, Republic of	Article 8.1	60	<p>It is stated that CNSC shall report to the Parliament currently through the minister of Natural Resources Canada and also CNSC get support of the minister of Natural Resources Canada when it seeks incremental funding.</p>	<p>The CNSC is independent from outside influence, including the federal government, in the conduct of its activities. The CNSC's decisions are not subject to review by the Minister or other parts of the executive. The CNSC is accountable to the public and to the Parliament through an annual report that is submitted to Parliament, which is submitted <u>through</u> the Minister of Natural Resources Canada. Conflict of interest guidelines also provide assurances that there is</p>

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				<p>Under this circumstance, how does CNSC ensure the regulatory independence from the Ministry of Natural Resources Canada which controls the licensees such as NRU and also has primary interest in operating the facilities?</p>	<p>distance between the Commission and stakeholders.</p> <p>The CNSC’s budget partially comes from Treasury Board through appropriation and over 70 percent of its budget is cost recoverable through the application of the <i>Cost Recovery Fees Regulations</i>. Effective April 1, 2009, CNSC receives its funding from two sources and they are:</p> <ul style="list-style-type: none"> • Fees paid by applicants, licensees and other special project sponsors in accordance with the CNSC Revenue Spending Authority approved by Parliament and applied in accordance with CNSC’s Cost Recovery Fees Regulations. The Commission has the statutory authority to prescribe and charge fees for the services, products and information that it provides under the NSCA, and the fees may not exceed the costs to the CNSC of its regulatory activities (ss. 44 (1), (2) and (3), 21(1)(g), NSCA); and • Parliamentary Appropriation: Where the CNSC, through the Treasury Board of Canada (i.e., the central government treasury from which all federal departments receive their operating budgets – appropriation funding) receives an authority from Parliament to expend resources from Canada’s treasury; Fees paid by applicants, licensees and other special project sponsors in accordance with the CNSC Revenue Spending Authority approved by Parliament and applied in accordance with CNSC’s Cost Recovery Fees Regulations. The Commission has the statutory authority to prescribe and charge fees for the services, products and information that it provides under the NSCA, and the fees may not exceed the costs to the CNSC of its regulatory activities (ss. 44

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					<p>(1), (2) and (3), 21(1)(g), NSCA)</p> <p>The parliamentary appropriation funds the CNSC activities related to applicants and licensees that are <u>fee-exempt</u> (such as hospitals, universities and other public institutions), activities related to international obligations (including safeguards activities in support of the non-proliferation of nuclear weapons), outreach and stakeholder relations activities, public responsibilities such as emergency preparedness, and the ongoing oversight of the NSCA and the associated regulatory framework.</p> <p>The incremental funding described in the report pertains to activities that have no direct benefit to individual licensees, thus, this situation is not a potential source of conflict.</p>
22	United Arab Emirates	Article 8.1	69	<p>The inspector training and qualification program for power reactor site inspectors seems to be a commendable practice by Canada. Please describe the details of the qualifications that each person must hold before an inspector card is issued.</p>	<p>The CNSC requires a Nuclear Power Plant inspector be qualified both academically and by on-job-training before receiving an inspector card. Each inspector is required to take courses related to the Regulatory Process, Technical CANDU Specifics, Non-technical (effective communications), Radiation Protection and Conventional Health and Safety. In addition, there is structured on-job-training program for completing inspections in the main control room, system inspections, program inspections and surveillance rounds. There is no set time limit to complete the training and an individual may only be accredited as an inspector once the site supervisor and Director is assured that the individual fully satisfies the required qualifications. Throughout the various phases of training the inspector must go through written examinations for courses and field evaluations for on-job-training. The on-job training evaluation is done by an independent evaluator. All training is documented and maintained throughout an individual's</p>

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					employment with the CNSC.
23	United Arab Emirates	Article 8.1	68	CNSC is to be commended for integrating succession planning with its formal Individual Learning Plan process.	Thank you for the comment.
24	United Arab Emirates	Article 8.1	55	Based on Canada’s experience, what measures has Canada taken to preserve their independent nuclear safety authority in the face of political pressures, media attention or national interests?	<p>The original legislation in Canada governing nuclear safety, the Atomic Energy Control Act of 1946, encompassed both regulatory and developmental aspects of nuclear activities. When the new Nuclear Safety and Control Act (NSCA) was enacted in 1997, the regulatory and developmental functions were separated in law. The NSCA (section 8) denominates the CNSC as the regulatory body in Canada. It clearly distinguishes its regulatory role from that of organizations involved in development, marketing, or utilization of nuclear energy or substances. No other authorities than the CNSC are involved in the licensing and the regulation of the safety aspects of nuclear activities.</p> <p>In terms of independence in making regulatory decisions, the CNSC is independent from outside influence, including the federal government, in the conduct of its activities. The CNSC’s decisions are not subject to review by the Minister or other parts of the executive. Conflict of interest guidelines provide assurances that there is distance between the Commission and stakeholders.</p> <p>The CNSC continues to maintain its authority as the single, independent nuclear safety regulator in Canada.</p>
25	United Arab Emirates	Article 8.1	55	Please clarify from Canada’s experience how best to utilize the expertise of independent experts (e.g., TSOs) in	As mentioned in Section 8.1 of Canada’s 5th report, the CNSC no longer makes use of standing advisory bodies (although there are provisions to allow it). CNSC has, on staff, a large contingent of highly-qualified technical and

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				<p>evaluating and making recommendations on technical or regulatory issues while still maintaining independence?</p>	<p>regulatory experts with expertise across many disciplines, as described in Section 8.1 b. Conflict of interest provisions, including ethics training, help reduce further the likelihood of undue outside influence on CNSC affairs. Although the wide knowledge base allows most issues to be assessed by staff “in house”, outside expertise is occasionally engaged for certain technical or regulatory issues. In these cases, it is still important to have a wide base of expertise within the CNSC to properly maintain “smart buyer” capability. Having adequate breadth and depth of knowledge to critically assess all types of recommendations from the outside is critical to assessing if the CNSC’s purposes are truly being served by the recommended position or course of action.</p> <p>When outside expertise is needed, it is typically engaged through the contracting mechanisms of the CNSC’s Research and Support Program. The contracting process ensures that contractors are fully qualified to provide the advice sought and are free of conflicts of interest that may provoke a challenge. Conflict of interest requirements are stated in contracts and a CNSC Contract Review Committee carefully reviews all contracts to ensure that the contractors are free from both real and perceived conflicts of interest.</p> <p>For some technical issues, the CNSC has also jointly sponsored, with the NPP licensees/industry, independent technical panels to review certain aspects of the issues, such as the analysis of effects associated with the issue or the proposed methodology to address the issue. An example is provided in Appendix G.3 of Canada's fifth national report, which describes an independent technical panel that reviewed a new neutron over-power analysis methodology to assess the slow loss-of-regulation event.</p>

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26	United Arab Emirates	Article 8.1	66	In the directorate of safety management there is a “Management Systems Division.” What is the role of this division with respect to the the Personnel Certification Division and the Human and Organizational Performance Division?	<p>The Divisions within the Directorate of Safety Management provide specialist advice in the assessment and implementation of regulatory programs in the areas of: human factors, human performance, organization and management, quality assurance, quality management and management systems, personnel certification, examination and testing and personnel training.</p> <p>The three Divisions referred to are integrated within the Directorate of Safety Management and provide specialist advice in the assessment and implementation of regulatory programs in the areas of: human factors, human performance, organization and management, quality assurance, quality management and management systems, personnel certification, examination and testing and personnel training.</p> <p>Their respective functions are:</p> <ul style="list-style-type: none"> • Management Systems Division provides technical expertise on the oversight of the management systems used by licensees. • Personnel Certification Division provides technical expertise in the certification process for licensee staff • Human and Organizational Performance Division provides technical expertise in Human Action, Human Performance, Human Factors and Organizational Performance assessment of licensees, this includes such areas the potential safety impacts of licensee proposed organizational changes and the area of licensee Safety Culture.
27	United Kingdom	Article 8.1	Page 67	The report describes extensive efforts to estimate staffing requirements, consider retirements and recruit and	The CNSC uses a systematic approach to training its employees. Although it does not have a formal competence management system, it has developed a uniform training and qualification program for inspectors (refer to Question

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				<p>train newcomers. Has this been a one-off ad hoc process or has CNSC now established a formal competence management system, within its overall management system, to deal with: using the overall strategic plan to systematically assess competence needs, in the near term and longer term future; and planning and delivering recruitment, training and other elements of competence development? Section 11.2 a (page 93) refers to the Systematic Approach to Training for licensees, is this approach used in CNSC?</p>	<p>#22 for details) which outlines the necessary steps necessary to qualify an individual to the requisite inspector certification through various formal courses and practical hands on training. The training program includes regulatory core training and service line specific training as well as on-the-job training experience. The CNSC is proactive in ensuring staff competencies remain current and regularly compiles and analyzes information of learning needs and gaps to plan learning activities across the organization. A similar process is in development for Regulatory Program Officers.</p>
28	United States of America	Article 8.1	8.1, p 68	<p>CNSC has been very successful in recruiting new staff over the past few years. What lessons learned and good practices regarding recruiting and hiring strategies can you share with other countries facing challenges in this area?</p>	<p>The CNSC in its efforts to become an Employer of Choice and increased its presence in various forums and focusing on youth. In parallel, it has developed targeted recruitment material, applied to Canada’s Top 100 Employers competition, increased its participation in external awards and advertised in multiple job sites. It also developed a staffing framework to provide hiring managers with as much flexibility and accountability as possible while respecting key values.</p>
29	China	Article 8.2	8, 55	<p>What progresses did the CNSC make in respect to the independency of its supervisory and regulatory within the time limit of the report.</p>	<p>During the reporting period, the CNSC continued to maintain its well-established authority as the single, independent nuclear safety regulator in Canada. This was enhanced by progress in areas that contribute to well-informed and transparent regulatory decisions. Progress in achieving openness and transparency in regulatory activities, as well systematically basing decisions on a</p>

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					<p>balanced approach to evaluation of all risks, are described in Section 8.2 b of Canada’s 5th report.</p> <p>See responses to questions 21 and 24 for additional information on regulatory independence.</p> <p>The CNSC is an independent quasi-judicial body that is mandated to regulate the use of nuclear energy and materials in Canada. It has exclusive jurisdiction in Canada over nuclear safety and is an independent agency of the Government of Canada. Its mandate, as set out in its enabling legislation, does not include regulating to meet political or economic objectives. The <i>Nuclear Safety and Control Act</i> (NSCA) enacted in 2000 as replacement for the <i>Atomic Energy Control Act</i>, reaffirmed the notion of independence by stating:</p> <p style="padding-left: 40px;">While the existing Act encompasses both the regulatory and developmental aspects of nuclear activities, this enactment disconnects the two functions and provides a distinct identity to the regulatory agency. It replaces the Atomic Energy Control Board with the Canadian Nuclear Safety Commission, underlining its separate role from that of Atomic Energy of Canada Ltd., the federal research, development and marketing organization for nuclear energy.</p> <p>Nuclear research and development and nuclear policy in Canada are two distinct functions which are governed under their own distinct enabling legislation, separate from the NSCA, they are:</p> <ul style="list-style-type: none"> • the <i>Nuclear Energy Act</i> for research and development by Atomic Energy of Canada Limited (AECL)

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
					<ul style="list-style-type: none"> • the <i>Department of Natural Resources Act, 1994</i> for the development of nuclear policy by the Minister of Natural Resources Canada <p>The CNSC is independent from outside influence, including the federal government, in the conduct of its activities. The CNSC’s decisions are not subject to review by the Minister or other parts of the executive. The CNSC is accountable to the public and to the Parliament through an annual report that is submitted to Parliament, which is submitted <u>through</u> the Minister of Natural Resources Canada. Conflict of interest guidelines also provide assurances that there is distance between the Commission and stakeholders.</p> <p>The CNSC’s budget partially comes from Treasury Board through appropriation and over 80 percent of its budget is cost recoverable through the application of the <i>Cost Recovery Fees Regulations</i>. Effective April 1, 2009, CNSC receives its funding from two sources and they are:</p> <ul style="list-style-type: none"> • Parliamentary Appropriation: Where the CNSC, through the Treasury Board of Canada (i.e., the central government treasury from which all federal departments receive their operating budgets – appropriation funding) receives an authority from Parliament to expend resources from Canada’s treasury; and • Fees paid by applicants, licensees and other special project sponsors in accordance with the CNSC Revenue Spending Authority approved by Parliament and applied in accordance with CNSC’s Cost Recovery Fees Regulations. The Commission has the statutory authority to prescribe and charge fees for the services, products and information that it

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					<p>provides under the NSCA, and the fees may not exceed the costs to the CNSC of its regulatory activities (ss. 44 (1), (2) and (3), 21(1)(g), NSCA)</p> <p>Full implementation of the Revenue Spending Authority (RSA) will represent the CNSC’s primary funding in future years. The parliamentary appropriation funds the CNSC activities related to applicants and licensees that are fee-exempt (such as hospitals, universities and other public institutions), activities related to international obligations (including safeguards activities in support of the non-proliferation of nuclear weapons), outreach and stakeholder relations activities, public responsibilities such as emergency preparedness, and the ongoing oversight of the NSCA and the associated regulatory framework.</p>
ARTICLE 9: RESPONSIBILITY OF THE LICENCE HOLDER					
	Argentina	Article 9	Pag.64	It was mentioned that changes in the plant personnel organisation are either subject to licensing by the licensing authority or to the approval of the supervisory authority (Article 9 – pag. 64). Please provide detailed information on the personnel organisation changes approval / authorisation process related to licensed personnel working on safety –relevant.	Withdrawn by originating country.
ARTICLE 10: PRIORITY TO SAFETY					
30	Argentina	Article 10	Section 10 c – Page 89	It was reported that CNSC staff use a process termed the organization and management	The organization and management (O&M) review method was developed by the CNSC in the late 1990s to provide an oversight of organization and management issues. The

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
				<p>review method to evaluate organizational influences on licensees' safety culture . 1) How using the above mentioned method can be assessed the organizational and management attitudes and behaviours related to licensees' safety culture? Please, if it is possible give some example of the method application. 2) Were developed/implemented some performance indicators to measure specific plant safety culture aspects?</p>	<p>method was developed over several years in which it was applied to a number of nuclear power stations and other facilities. Safety culture was one factor assessed by the O&M review method but was revealed by Factor Analysis to be the best predictor of safety performance. In addition the safety culture framework, which is based on 16 performance indicators linked to six distinct safety culture characteristics, is used to assess organization and management weaknesses which are involved in reportable events.</p> <p>See response to Question #32 for more information on potential performance indicators for Safety Culture.</p>
31	China	Article 10	10, 87	<p>Would you please provide further explanations on the positive enhancement or impact brought by safety culture reviews conducted by Canada NPPs within the time limit of the report?</p>	<p>The CNSC encourages the NPPs to conduct their own safety culture self-assessments (SCSAs). There were two notable assessments conducted during the period of the report. The first when an NPP identified a major weakness in its safety systems which had not been recognized for several years. Some of the causes for this weakness were ascribed to the organization's safety culture. A self-assessment was conducted, the specific weaknesses identified and a detailed corrective action plan developed to deal with all the related issues. The second instance occurred when the Commission requested that CNSC staff conduct a separate safety culture assessment which was done in collaboration with an independent contractor using the CNSC's Organization and Management Review method. The results of both the SCSA and the CNSC assessments were compared. The comparison revealed general agreement and specific opportunities for improvement in both methods. The advantage of the self-assessment clearly lies in the fact that since the NPP</p>

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					conducted the assesment the results and outcome are likely to be accepted more easily.
32	Germany	Article 10	Page 89, 10.d last paragraph	It is stated “This requires the development of performance indicators to manage safety culture improvement from current status to new targets.” Please elaborate how indicators can be used to “manage” safety culture improvements.	Safety culture is a concept which refers to attitudes and perceptions but which cannot be regulated in themselves. However, the safety policies, the behaviour of leadership, the speed and depth of response to the raising of safety concerns are all behaviours which are both determined by the culture and which, in their turn affect the expectations and attitudes of others. The “performance indicators” referred to in the document are “leading” signals of perceived weakness and refer to observable performance of people at different levels of the organization. Quantitative counts and qualitative assessments of proactive leadership, effective development and adherence to safety procedures by middle management and careful work practices by workers can be used as indicators. However, it is important to recognize the safety culture is more than one set of attitudes or types of behaviour and can only be promoted, strengthened and maintained by a concerted effort by staff at all levels.
33	Germany	Article 10	Page 89, chap. 10 c, second last paragra	It is stated “The CNSC draft document Guidance for Licensee Self-assessment of Safety Culture has been distributed to NPP licensees for guidance, and was used as a framework for commenting on selfassessments done by several facilities.” Does CNSC plan to follow the self-assessments of the NPPs? Is it planned to perform regular inspections or assessments of these selfassessments?	<p>The CNSC examines documents describing the licensees proposed self-assessment approach and reviews plans to conduct specific assessments, and critiques the results collected. The NPPs are provided feedback on planned corrective action plans (CAPs) that may arise from the CNSC’s reviews.</p> <p>The CNSC’s approach towards self-assessments is not prescriptive. This means CNSC does not apply “compliance” per se to Safety Culture Self Assessments. The CNSC draft document Guidance for Licensee Self-assessment of Safety Culture outlines the key elements to ensure that the method used conforms to some basic criteria, such as “being able to withstand review by peers”, “being</p>

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					practical” etc.
34	Romania	Article 10	section 10 c	How does the CNSC regulate the management of organisational change (i.e. has the CNSC issued any specific guidance to licensees on this matter)?	<p>CNSC Staff reviews licensee management and organizational change procedures and conduct inspections to evaluate the effectiveness of their implementation. Guidance is provided through change control criteria established in the Canadian Standards Association (CSA) Standard N286 <i>Management System Requirements for Nuclear Power Plants</i> which is a licensing requirement integrated into the NPPs operating licence. IAEA Standards and Guides such as GS-R-3 <i>The Management System for Facilities and Activities</i> and NS-G-2.4 <i>The Operating Organization for Nuclear Power Plants</i> provide additional, but non mandatory guidance.</p> <p>At the time of licensing or licence renewal, an applicant is required by regulations to provide a detailed description of his operating organization. CSA N286-05 includes several measures related to organizational changes, and the CNSC in its review will pay particular attention to the way nuclear, radiological and conventional safety responsibilities are managed and integrated within the general management system. Once approved, each substantive change proposal thereafter must be submitted to the CNSC and a document describing the change and its impact on the organization charts before and after the change must be presented. The CNSC may request further clarification from a licensee before accepting the change if there is a possible safety risk.</p>
35	Romania	Article 10	section 10 c	What specific training is provided to CNSC inspectors in order to assist them in recognising issues relevant to safety culture in the licensees’ organisations, including signs of declining safety	<p>There is no specific course that develops an inspector’s safety culture awareness. Inspectors acquire this awareness through a structure on-the-job training approach and mentoring by senior inspectors.</p> <p>To date inspections have involved Organization and Management expertise in the inspection teams and a new</p>

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
				performance?	<p>approach to the qualification of inspectors through some basic training on the topic of safety culture, some of the signs of a weakening health in safety culture and some guidance on when to involve specialist to enhance inspections. Special training and checklists for site inspectors is also being considered to allow them to more easily detect indicators of the health of the safety culture through regular inspections or in the course of surveillance.</p>
36	Switzerland	Article 10	89	<p>The report says that the CNSC is in the possession of a review process to evaluate organizational influences on licensee’s safety culture. The method used to conduct this process is indicated to be validated, objective and systematic. Which are the criteria or method(s) this process was validated against? How do you ensure objectivity when CNSC staff is executing this process and analyzing/interpreting the data gained from it?</p>	<p>The CNSC Organization and Management (O&M) Review method was developed in collaboration with an outside contractor who used the results of several assessments to identify the factors which best predicted the health of safety culture. The method also uses several concurrent but different methods to assess safety culture. The use of surveys, interviews and observations allowed cross verification.</p> <p>The use of an outside contractor to help conduct safety culture assessments has provided an added level of objectivity when reviewing the data collected and when determining the wording of weaknesses we uncover.</p>
37	United Arab Emirates	Article 10	89	<p>An event in 2009 identified possible weaknesses in the organization’s safety culture. Please provide the elements of the corrective action plan. What is the “organization and management review method”?</p>	<p>The weaknesses in the organization’s safety culture were identified in a safety culture self-assessment and in the root cause analysis following a severe leak. The fact that these two methods pointed to the same weaknesses stressed the importance and validity of the issues. The CNSC asked for both a prioritization of the actions and an itemized corrective plan to address them.</p> <p>The organization and management (O&M) review method was developed by the CNSC in the late 1990s to provide an</p>

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
					oversight of organization and management issues. The method was developed over several years in which it was applied to a number of nuclear power stations and other facilities. Safety culture was one factor assessed by the O&M review method but was revealed by Factor Analysis to be the best predictor of safety performance along with the safety culture framework used to assess organization and management weaknesses which are involved in reportable events.
38	United States of America	Article 10	10c, p 89	The report references the organization and management review method as a means of evaluating organizational influence on licensees’ safety culture. Is this method used on a recurring basis as part of a routine inspection plan, or is it mainly employed in response to events where safety culture is a causal factor?	<p>The organization and management (O&M) review method has not been used systematically and recurrently. It is not part of an “inspection plan” since the approach of the CNSC towards Safety Culture is to promote and not to enforce “a compliance approach”. An O & M assessment is performed when the CNSC identifies the need to perform it.</p> <p>It is available and used as an element in the review of the NPP before license renewal, which in Canada is done every few years. As correctly identified in the question, the method is also employed in response to events where safety culture is a possible causal factor.</p>
ARTICLE 11: FINANCIAL AND HUMAN RESOURCES					
39	United Arab Emirates	Article 11.1	9	Please describe measures that are being taken or planned in Canada to address the large numbers of retirements of experienced personnel from the nuclear sector.	<p>The large turnover rate previously anticipated within the CNSC has not materialized as the number of actual retirement has been below forecast. However, the CNSC has focused on identifying critical management positions that may be at risk due to retirements and has adopted a corporate talent management approach whose goal is to identify those positions at risk and to recommend appropriate corrective actions to senior management.</p> <p>In the near term, the CNSC has developed and implemented</p>

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					a successful Alumni Program and has created a corporate succession planning fund to enable knowledge transfer and sound succession planning.
40	United Arab Emirates	Article 11.1	100	How does a good practice become an important practice. Please give an example.	The question is not understood. There is no reference to “important practices” in the context of p. 100 of the report.
41	Argentina	Article 11.2	Section 11.2a – Page 93	Related to training and certification of workers, it was reported that a criteria to measure training effectiveness are being put in place (Article 11 - Section 11.2a – page 93). Could be detailed each criteria used and the corresponding results/experience of their implementation?	Many licensees are still in the process of implementing criteria to measure training effectiveness, so it’s difficult to comment on the experience of the industry as a whole. However, as a specific example, Bruce Power uses the Kirkpatrick Model for learning evaluation. To evaluate training development requirements, a “Training Effectiveness Evaluation Worksheet” is used to identify the issue driving the need for training and to determine specific training topics, the expected results and the preferred method to evaluate training effectiveness. There are a number of criteria to measure the effectiveness of the training. These could include: trainee knowledge evaluation (written exam), trainee performance evaluation (lab, on the job evaluation, etc), performance indicator reviews (i.e. human performance), focus area self assessments, field observations, interviews, supplemented assessments (internal nuclear oversight, peer reviews) and others. These criteria are set up during the development of the training and will differ depending on the expected results and behaviours that the training is designed to deliver. For example, Bruce Power has seen some positive results since instituting this method of training effectiveness evaluation in 2008.
42	Germany	Article 11.2	Page 93, chap. 11.2a, 4th paragraphe	Common training courses between regulatory body and industry are a remarkably good practice.	Thank you for the comment.
43	United Arab	Article	93	We have noticed that the	The licensees’ training programs are not described in detail

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	Emirates	11.2		operating experience factor of the training program is not mentioned. Is that because in Canada the TSOs are handling the operation experience responsibility? And, if that is the case, how do you as the regulator ensure that the TSOs are analyzing the pertinent reports ?	in Section 11.2 of the report because they cover a very large number of technical and other areas. Certain broad categories are briefly described – operations, maintenance, radiation protection, and regulatory affairs. Although OPEX practices are not mentioned, they are, in fact, also covered in the curriculum of licensee training courses. Furthermore, the contents of licensee training courses are also updated regularly to reflect changes in experience, information, practices, etc.
ARTICLE 12: HUMAN FACTORS					
44	India	Article 12	12 c, Page 104	What is the minimum time considered for operator to take action in case of any transient or emergency conditions?	<p>Following the first clear and unambiguous indication of the necessity for operator actions, such actions may normally be credited in safety analysis level-3 defence in depth no sooner than:</p> <ul style="list-style-type: none"> • fifteen (15) minutes for actions in the main control room • thirty (30) minutes for actions outside the main control room (RD-337 <i>Design of New Nuclear Power Plants</i>, section 8.10.4) <p>It should be shown by assessment that the specified times are sufficient for the operator to detect, completely diagnose and carry out the required actions. Such assessment should account for the following:</p> <ul style="list-style-type: none"> • time starting from the occurrence of the initiating event to the receipt of the event indication by the operator • time to carry out the diagnosis

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					<ul style="list-style-type: none"> • time required to perform the action • time for the safety related function to be completed <p>In certain circumstances, time shorter than 15 minutes might be assumed provided that:</p> <ul style="list-style-type: none"> • the operator is exclusively focused on the action in question • the required action is unique and does not involve a choice from several options • the required action is simple and does not involve multiple manipulation • <p>The assessment of the credited operator action items should be formal and include a validation process. Such a process could consist of:</p> <ul style="list-style-type: none"> • documented procedures that define specific operator action entry points and action • training of all station shift operators on those procedures • performing station drills for recording and assessing the response time • an assessment of those response times and an evaluation done to provide a time credible for safety analysis usage.

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45	Korea, Republic of	Article 12	Section 12 c	<p>According to the descriptions of section 12 c, the human reliability analysis is considered to estimate the probability that a system-required human action, task, or job required for safety will not be completed successfully within the time period. And licensees use industry-accepted human reliability analysis methods within their PSAs. What are the regulatory positions for assuring the appropriateness of the results of human reliability analysis in the qualitative and quantitative aspects which will be performed by licensee?</p>	<p>The CNSC does not require that its licensees use a particular method to calculate the Human Reliability Analysis (HRA), but rather verifies that the HRA method chosen meets the requirements of CNSC Standard S-294, <i>Probabilistic Safety Assessment (PSA) for Nuclear Power Plants</i>, and that they are done in an industry-recognized and systematic way. One method frequently used is the Technique for Human Error Rate Prediction (THERP).</p>
46	Korea, Republic of	Article 12	Section 12d	<p>According to the description of section 12 d, to ensure that the operations and maintenance procedures are fit for purpose and to develop technical steps in the procedures, the license should use information from task analyses. What are the regulatory positions for ensuring the appropriateness of the scope and methodology of task analysis which will be performed by licensee?</p>	<p>The CNSC requires the licensee to demonstrate the logic behind its procedures and a well developed task analysis is a good way to demonstrate this. The word SHOULD is used to indicate that a task analysis is not mandatory and no method is specified although the method used is required to be explained if it is conducted.</p>
47	Switzerland	Article 12	224 (Annex 12b)	<p>The report says that in the Canadian nuclear industry,</p>	<p>From an industry point of view, AECL develops a Human Factors review plan for each modification to a system or</p>

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				<p>HFE principles are applied in e.g. modifications to existing NPPs. Please describe these principles as well as the proceeding to integrate them into the plant modernisation process?</p>	<p>group of systems for a refurbishment project. The plan has 12 elements and is based on the USNRC NUREG 0711 <i>Human Factors Engineering Program Review model</i>. The elements that are included are: HFE Program Management, Operating Experience Review, Functional Requirements Analysis and Function Allocation, Task Analysis, Staffing and Qualification, Human Reliability Analysis, Human-System Interface Design, Procedure development, Training Program development, Human Factors Verification and Validation, and Design Implementation (Integration) and Human Performance Monitoring.</p> <p>The last element - Human Performance Monitoring is beyond the scope of our program plans for refurbishment or new build projects but is included in the program for completeness and implementation by the licensee.</p> <p>From a regulatory point of view, the CNSC expects that Modern HFE principles using best HF practices will be consulted when considering plant modifications although it is recognized that the existing technologies, space limitations and control room practices may limit their application to older plants. The CNSC requires that each licensee indicate that modern principles were considered and further explain how they are applied and why they may be inapplicable in specific instances.</p>
48	Switzerland	Article 12	102-107	<p>To what extent other technical areas than human factors in design (12b), particularly work organization and job design (12e) as well as organizational performance (12g), are being considered by CNSC for new build projects? In other words:</p>	<p>The CNSC is aware of the potential for inadequate training, and worker oversight to result in human performance, and nuclear safety culture impacting the material quality of the plant during construction. The CNSC is working to increase awareness of the importance of human and organizational performance to nuclear safety in design, construction and commissioning even before nuclear materials are present.</p>

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				<p>is CNSC’s approach to considering human and organizational factors in new NPPs limited to consideration of human factors in design or are aspects such as the development of the future operating organization, consideration of human factors during construction, development and evolution of the project organization throuout the whole project etc. subject to CNSC’s oversight and formulation of requirements as well?</p>	<p>The CNSC has emphasized human and organizational factors throughout CNSC Regulatory Guide, DRAFT RD/GD-369 <i>Licence Application Guide: Licence to Construct a Nuclear Power Plant</i> and has also emphasized the importance of demonstrating the knowledge, skills and abilities of the applicant, the vendor, major contractors, and their sub-contractors and safety culture.</p> <p>The CNSC will continue to focus on human and organizational factors throughout the whole project.</p>
49	United Kingdom	Article 12	Page 103	<p>The Canadian Fourth Report (Page 69) stated “In the next reporting period, CNSC staff will continue to monitor closely the incorporation of HFE in the design and modification process, staffing levels and limits to hours of work. These factors may become even more important because of the increased activity in the industry and a shortage of qualified personnel in many disciplines. The increasing reliance on the use of contracted staff at the NPPs, and the necessary management and oversight thereof, will also</p>	<p>With respect to the first question, the CNSC observed a continuing difficulty of licensees being able to source suitably qualified Human Factors personnel to conduct the analysis of requirements and the creation of purchasing requirements for modifications. The reference to “expanding the approach to address human performance at an organizational level” refers to improving licensees’ understanding of the breadth of human factors which can influence human performance.</p> <p>In regards to leading indicators, it is true that overtime working can indicate a response to increasing time pressures or can result from excessive delays. This can be a “leading” measure of an increasing probability of risk or of decreasing safety.</p> <p>In relation to the length of shifts worked by NPP staff, the CNSC is currently developing its regulatory oversight</p>

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				<p>be an area of focus”. Can Canada explain what was the outcome of these monitoring activities and how it relates to the statement in the fifth report, page 103 “CNSC staff is working with licensees to expand the approach to address human performance at an organizational level”? The report also states “CNSC staff is also investigating useful leading indicators of human performance that accurately reflect safety performance, rather than relying on lagging indicators (such as event-free days)”. Is one of these indicators related to overtime working? Has CNSC required from licensees a demonstration that the lengths of shifts worked by NPP staff do not introduce deleterious fatigue?</p>	<p>regarding “hours-of-work” in an effort to reduce the possibility of fatigue.</p>
ARTICLE 13: QUALITY ASSURANCE					
50	Germany	Article 13	Page 110, chap. 13.c, last paragraph	<p>It is stated “It is expected that new integrated management system requirements will be gradually implemented over a few years.” How often will the regulatory body assess the management system of the licensee? What are the potential requests or sanctions,</p>	<p>The CNSC designed its compliance program to continually assess a licensee’s management systems. However, due to the size and complexity of licensee organizations, compliance reviews and inspections only address specific elements of the management system over the licensing period (currently, five-years typically) so that an overall view is obtained prior to license renewal.</p> <p>Major deficiencies are dealt with in the same way as other</p>

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				if the assessments reveal major deficiencies?	non-compliancees through the issuance of Action Notices or Directives, depending on the nature of the deficiency, requiring corrective and preventive actions implemented consistent with an agreed timeline. For extreme cases, a Designated Officer can issue an Order to a licensee for immediate corrective actions, but to date this has not been necessary. Shortened licensing periods and operating restrictions are also additional options that may be considered.
51	United Kingdom	Article 13	Page 111	The report states that integrated management systems are to be introduced in NPPs aligned to GS-R-3 and mentions the management of organisational change and continuous improvement. How are these activities organised at the moment and how does CNRC judge the adequacy of licensees arrangements?	<p>The majority of NPP licensees have implemented a management system that integrates the various business and regulatory requirements consistent with CSA N286-05 <i>Management System requirements for Nuclear Power Plants</i>. The phased-in approach relates more to the non-NPP (i.e. Class 1A and 1B facilities and Uranium Mines and Mills) where separate quality, environment, and health and safety programs tend to exist.</p> <p>NPP licensees have procedures for the management of organizational changes and are expected to continuously improve their management system. For example, OPG's management system is aligned with Canadian Standards Association CSA N286 "Management System requirements for Nuclear Power Plants" standard as a condition of our plant power reactor operating licences.</p> <p>This management system includes the processes for both the management of change and continuous improvement. As part of this management system, these managed processes are subject to regular monitoring and reporting to assess effectiveness and identify opportunities for improvement.</p> <p>CNSC Staff review these processes and conduct inspections to evaluate the effectiveness of their implementation. The</p>

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					<p>improvement and evolution of licensees’ management systems are evaluated over the course of the licensing period.</p> <p>Guidance is provided through change control and continuous improvement criteria established in CSA N286 which is a licensing requirement. IAEA Standards and Guides such as GS-R-3 and NS-G-2.4 provide additional, but non mandatory guidance.</p> <p>With the evolution to the new management system requirements, CNSC Staff have engaged licensees on this topic to better share understanding and expectations. The CNSC is also committed to continuous improvement through the review and evolution of its compliance program.</p>
ARTICLE 14: ASSESSMENT AND VERIFICATION OF SAFETY					
52	Argentina	Article 14.1	Section 14(i) c – Page 118	<p>In the Report was mentioned (Article 14 - Section 14(i) c – page 118) that licensees who are planning life extensions are required to carry out an integrated safety review (ISR) based on the IAEA periodic safety review (PSR) guide (NS-G-2.10). Please, could you explain the main differences and similarities between an ISR and a PSR? What are the advantages of using ISR instead of PSR?</p>	<p>An ISR is the same as a PSR except that it is only performed once in preparation for a life extension project (i.e., it is a safety review that is not periodic). The conduct of an ISR has the same benefits as the conduct of a PSR.</p>
53	China	Article 14.1	14.(i), 112	<p>As per the analysis and evaluation, safety issues of candu reactor are classified as</p>	<p>CNSC staff is currently tracking 13 outstanding Category III issues. Resolution of most of those issues is nearing completion. In order for an issue to be closed or re-</p>

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				category 1/2/3 and subsequent evaluation and disposal will be conducted based on category. This is very meaningful and will contribute a lot to increasing the safety confidence of the reactor, how does it progress? Shall we consider to share the results and benefits among the candu reactors in some certain way?	<p>classified to a lower category, the licensee must demonstrate that the risk control measures (or corrective actions) taken or committed in accordance with an accepted schedule, are such that the risk significance level posed by the issue is reduced. Activities vary from research and development programs to more analyses aimed at reducing uncertainties.</p> <p>The CNSC report describing the Category III issues and the required risk control measures was produced in August 2009 and is a publicly-available document. Copies of that report were distributed to the CANDU Senior Regulators at their 2009 meeting.</p>
54	China	Article 14.1	14.(i), 119	There are several Canada NPPs under refurbishment which requires long working periods and big amount of funding, so how to make a good balance between the economics and safety?	An integrated safety review was completed as per requirements of the CNSC Regulatory Document RD-360 <i>Life Extension of Nuclear Power Plants</i> . This review ensures safety considerations are met. The economics were assessed by performing a cost /benefit analysis, this analysis became part of the business case for the refurbishment project to ensure that a balance between economics and safety is attained.
55	Germany	Article 14.1	Page 115, section 2	For the licensing of Darlington, the CNSC consultative regulatory document Requirements for the Safety of CANDU Nuclear Power Plants (C-006) was used on a trial basis. What are the results? Are there any results for the other Canadian Nuclear Power Plants?	<p>The results of the application of C-006 <i>Safety Analysis of CANDU Nuclear Power Plants</i> on a trial basis can be found in Part 3 of the Darlington Safety Report 'Accident Analysis', the latest version of which was issued in 2009, it having been updated every three years since its original issue.</p> <p>The Accident Analysis demonstrates that the requirements for single and dual failures contained in C-006 are met. The assumptions made in the safety analysis when demonstrating that the requirements are met form the basis for the safe operation of the Darlington NPP. The limits and conditions associated with the safety requirements</p>

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					<p>constitute the Safe Operating Envelope.</p> <p>The original version of C-006 (Rev 0) has not been applied on any other station. However, in 1999, C-006 (Rev 1) was issued, updating the original to reflect the philosophy of the new Nuclear Safety and Control Act and its Regulations that came into effect in 2000. C-006 (Rev 1) has been used as one of the 'modern standards' against which Canadian plants have been compared when being refurbished. Pickering A, Bruce A, Point Lepreau and Pickering B have used it in this manner. This is no longer the case, since the CNSC has now published RD-310, which supercedes C-006 and is being used as one of the 'modern standards' against which Darlington is being compared as it is being prepared for its refurbishment. RD-310 is consistent with IAEA NSR-1.</p>
56	India	Article 14.1	Annex 14(i)c Page 234	<p>It is stated that in Point Lepreau, one of the design change specifically for severe accident is – containment emergency filtered venting. In this context, please explain i) How does timing of this SAM action compare with actions in public domain as per emergency plans? ii) For accepting this as a SAM action, was consequence estimation done and if so up to what distance?</p>	<p>The Containment Emergency Filtered Venting System, installed at Point Lepreau to facilitate severe accident management, would be used only to mitigate the risk of containment failure due to severe overpressure which might arise during the course of a severe accident. As such the comparison is between controlled releases through an engineered filtration system intended to be capable of removing a significant proportion of the non-noble gas fission products, and uncontrolled unfiltered releases of fission products from a containment system breached by the consequences of severe overpressure.</p> <p>As such the criteria for use are solely on the basis of seeing a very high containment pressure indicative of imminent building failure. This is a final mitigation barrier where no other means of reducing containment pressure (without releases) are available and effective. Scenarios which might require the use of the emergency filtered venting system are</p>

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					<p>for the most part not anticipated to occur until at least 15 hours from the start of an event.</p> <p>A worst case scenario might lead to a need to use the system after about 5 hours into an event. It is anticipated that the Provincial Emergency Plans for evacuation could be fully implemented within 5 hours of an event. Emergency Plans and measures include the pre-distribution of iodine, an extensive public information program, a state of the art local notification system to warn individual home owners and a comprehensive local area evacuation plan. Combined with the relatively low population density around the plant, public evacuation of the zones near the plant is expected to be practical and effective prior to any anticipated need to release through the emergency filtered venting system.</p> <p>The alternative to the acceptance of this SAM action is to do nothing and to allow the containment to fail due to overpressure, with the resultant consequence of uncontrolled unfiltered releases. In all cases, the use of the containment filtered vent system significantly reduces the doses to the public compared to this alternative. The system would only be used where the option of retaining the fission products and not releasing is no longer an available option.</p>
57	India	Article 14.1	14(i)a, Page 116 (Para.3)	The earlier licensing practice wherein single and dual failures were considered, reference dose limits for dual failures were 250 mSV (WB) and 2500 mSV (Thyroid). In CNSC consultative document (C-0006), the dose limit for class-5 events is 250 mSV(Effective). As per these	At present, the safety analyses conducted in support of existing NPPs operating in Canada are not aligned with new regulatory documents, such as RD-337 or RD-310. RD-337 sets out CNSC expectations for the design of new water-cooled NPPs, whereas RD-310 was written to be applicable to both existing and new plants. Implementation of RD-310 for existing NPPs is expected to be phased in over several years, but no formal positions have been as yet developed on many specific details. In the new regulatory framework, there is no explicit requirement to analyze such dual failure

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				<p>documents it was required to be shown that event sequence like LOCA with LOECCS meet these dose limits. With issue of RD-337 (where dose limits for AOO and DBA are specified as 0.5 mSV and 20 mSV respectively) and RD-310 (where event classification cut off frequency for AOO and DBA are given as 10-02per reactor year and 10-05 per reactor year respectively), what would be resolution of event sequences like LOCA with LOECCS while aligning safety analysis of existing reactors with these new documents</p>	<p>events as LOCA with LOECCS deterministically. Nevertheless, the contributions of such events to risk are evaluated through PSAs.</p>
58	India	Article 14.1	Annex 14 (i) b, Page 230	<p>It is stated that in 2009 revision of Pickering PSA level-1, the estimated severe core damage frequency is 3.6×10^{-5} per year. It is noted that RD-337 was issued in 2008 where significant core damage frequency is stipulated to be lower than 1.0×10^{-5} per year. In view of this whether any design improvement was contemplated or whether for operating NPPs targets existing prior to issue of RD-337 will continue to be applicable.</p>	<p>RD-337 applies only to new reactors constructed after the issue date of RD-337, and hence does not apply to Pickering or Darlington NPPs. However, OPG's current Risk and Reliability (R&R) program (N-PROG-RA-0016) sets both a target for SCDF ($< 10^{-5}$ per year) and a limit for SCDF ($< 10^{-4}$ per year). Therefore the OPG target is consistent with RD-337. In situations where the estimated SCDF exceeds the target, but meets the limit (such as the case with Pickering), the OPG R&R program requires us to investigate the implementation of cost-effective measures to meet the target. This evaluation will be completed as part of the overall Operational plan to end of life for Pickering.</p>

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59	India	Article 14.1	Para 3 (3rd bullet) Page 115	<p>Safety Analysis Methods and Acceptance Criteria for Operating NPPs: It is mentioned that combinations of postulated initiating events with failures of mitigating systems (not just the classical dual failures) were explicitly required to be considered. What is the basis of considering the combination of PIEs with failure of mitigating systems and whether it is based on frequency of occurrence?</p>	<p>Certain combinations of PIEs with failures of mitigating systems were required to be considered by the consultative regulatory document C-006, which was used on a trial basis for licensing of Darlington NPP. The approach adopted in this document was deterministic rather than a probabilistic one, since at the time when C-006 was issued PSA was not viewed as a mature methodology. See also answer to Question #60.</p>
60	India	Article 14.1	Page 196, Appendix-G:	<p>G.2. CANDU Safety Issues Associated with LBLOCA: It is mentioned that unlikely combinations of events, such as LBLOCA combined with unavailability of ECC have been considered in the design of the CANDU reactors. Even though these event combinations are considered by other jurisdictions to belong to the beyond design basis accident (BDBA) category, they are currently treated as DBA in the Canadian regulatory framework. Please clarify i. Are these combinations considered as part of design basis? ii. Is there any reason why events</p>	<p>As part of the single-dual failure approach used previously, it is true that certain dual failures, such as LBLOCA combined with the unavailability of ECC, had to be analyzed deterministically. The new regulatory approach, which is based on RD-337 and RD-310 documents, allows re-classification of these events to BDBA, and analysis in the the context of the periodic safety goals.. The previous approach will be revisited along with the planned adoption of RD-310 for existing, operating NPPs in Canada. See also answer to Question #59.</p>

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				<p>belonging to BDBAs as per other jurisdiction are considered as DBAs for CANDUs? Whether this approach will be re-visited for the new reactors in the light of requirements given in RD-310, which requires events with occurrence frequency of $<10^{-5}$ per year to be considered as BDBA?</p>	
61	Pakistan	Article 14.1	Annex 14 (i)b , Page-230	<p>Can Canada clarify why the scope of PSAs of nuclear power plants at Bruce A and B, Point Lepreau and Gentilly-2 does not include internal hazards (internal fires, internal floods etc) PSA.</p>	<p>Point Lepreau includes internal hazards, fire and flood in the PSA work. This is stated on page 231 of the Canadian National Report.</p> <p>The PSAs for the Bruce A, B Point Lepreau and Gentilly-2 stations do include internal flooding however; the PSAs for all Canadian facilities are being (or have been) updated to meet the requirements CNSC Regulatory Standard S-294 Probabilistic Safety Assessment (PSA) for Nuclear Power Plants.</p> <p>Point Lepreau considers fire and seismic in its PSA while the Gentilly-2 PSA includes fire.</p> <p>While Bruce A and B currently do not have fire and seismic in their PSAs, they are in the process of being added to the scope of the PSA as part of transition plan to S-294 compliance. Fire was not originally included as there was no regulatory requirement to include fire prior to the issuance of S-294.</p>
62	Pakistan	Article 14.1	Section 14(i)b, Page 117	<p>The Use of PSA for online risk monitoring in Point Lepreau and Darlington NPPs is a very</p>	<p>OPG foresees the increased use of both on-line and off-line PSA tools to manage operational risk and to assist in operational planning activities. In the case of our other site</p>

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				positive step. Is there any plan to use PSA for online risk monitoring for other NPPs in Canada. Moreover, please explain whether PSA model is used with some specific changes for online risk monitoring or used as it is.	<p>(Pickering), we do not foresee installation of on-line “risk monitors” in the main control room environment, but rather see the use of such tools in maintenance planning activities and the like.</p> <p>Risk monitoring tools are implemented based on the PSA with minimal changes to equipment modelling.</p>
63	Pakistan	Article 14.1	Annex 14 (i) a, Page 229	Severe accidents are not shown in the list.	A typical safety analysis report for an existing Canadian NPP does not include a specific section devoted to the analysis of severe accidents. This analysis is conducted as part of the Integrated Safety Review to decide on the scope of refurbishment activity. However, the CNSC expects severe accidents to be addressed in Level 2 PSA. When the regulatory document RD-310 is adopted for existing NPPs, its expectations with respect to severe accidents will be required to be addressed in the safety analysis reports.
64	Ukraine	Article 14.1	Para 14.i Page 113	Do you use Risk Monitors in the RIDM process?	The RIDM process does not use risk monitors. The process uses risk notices to assess the overall additional risk posed by an issue.
65	United Arab Emirates	Article 14.1	112	The CNS National Report reports that three other regulatory initiatives — licensing basis definition, reformed licence, and licence condition handbook — have helped improve the clarity of requirements and expectations for NPP licensees, and have also facilitated increased regulatory efficiency and effectiveness. Are these new requirements that did not have to be met by previously	<p>None of these initiatives resulted in the creation of new requirements, <i>per se</i>, for any licensee. However, they have helped clarify the requirements already in place.</p> <p>Clarifying the definition of the licensing basis has helped to distinctly identify the boundaries of the information on which the decision to licence a facility (in the past, present, or future) is based). The reformed licence and licence condition handbook simply represent a restructuring and clarification of the information and requirements that were previously in all licences. In the current reporting period, it is planned that all NPP operating licences will be replaced by a licence in the new format and a corresponding licence condition handbook. These changes, in themselves, will not</p>

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				licensed reactors? Will existing NPPs be required to address these new criteria (backfit)?	introduce new requirements. However, the new licence contains generic licence conditions that refer to licensee program and references either a regulatory document or an industry standard. In this way eight new standards were introduced for the re-licensing of Bruce A and B reactors.
66	United Arab Emirates	Article 14.1	112	In 2008, the CNSC document, Design of New Nuclear Power Plants (RD-337), was issued to set out technology-neutral expectations for the design of new water-cooled NPPs. To a large degree, RD-337 represents the CNSC's adoption of the tenets in IAEA document Safety of Nuclear Plants: Design (NS-R-1), and the adaptation of those tenets to align with Canadian practices. Does the CNSC believe that this document would be a useful reference for Periodic Safety Reviews in Canada?	<p>Yes, RD-360 would be a useful reference for periodic safety reviews (PSR) in Canada.</p> <p>If Canada adopts PSRs, they will be conducted in the same way as integrated safety reviews (ISR) for life extension projects. The requirements for ISRs are described in CNSC document RD-360, which states that ISR includes a review against modern standards and practices to assess the level of safety compared to that of modern NPPs. Modern standards are those documents that define the set of high-level objectives and requirements for the siting, design, construction, commissioning, operation and decommissioning of an NPP if it were to be built at the time of the initiation of the life extension project. Clearly, RD-337 is such a document, and hence it is already being used as a reference in an PSR.</p>
67	United Arab Emirates	Article 14.1	112	The IAEA Integrated Regulatory Review Mission (IRRS) in 2009 reported that it was impressed with the extensive preparation of all CNSC staff. What advice could CNSC provide to FANR with regard to requesting and scheduling an IAEA IRRS Mission to UAE, and taking the necessary steps to be	<p>An important factor in the success of the IRRS mission to Canada was the commitment, from the outset, of high-level CNSC management to all the arrangements and inputs that were necessary. This commitment, and the importance of the mission, was well communicated to all levels of management and staff.</p> <p>Prior to the IRRS mission, the CNSC developed the Harmonized Plan of Improvement Initiatives (HP) to consolidate responses to lessons learned from previous audits and assessments. Consolidating the understanding of</p>

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				<p>prepared for the visit to make it as effective as it seems to have been in Canada?</p>	<p>strengths and weaknesses, <u>before</u> the mission, is very important. During the mission, the CNSC provided input and feedback to the review team to ensure that the output (e.g., the recommendations and suggestions) was organized and detailed in such a way as to easily facilitate further constructive efforts to improve. The HP was also developed as a flexible, “evergreen” mechanism. When the IRRS mission identified new issues or clarified CNSC’s understanding of other issues, it was relatively easy to address any needed improvement efforts in the context of the HP, thus ensuring the relevant initiative received the appropriate priority and resources in the context of overall CNSC operations.</p> <p>The actual mission is brief, so the quality of the findings will depend greatly on the quality of the input. When preparing, it is important that the regulator takes the self-assessment as seriously as the mission itself. The conduct of the self-assessment will be a learning experience, and the end product should be thoroughly reviewed prior to submission to the IRRS team. CNSC was able to do this, and it is worth noting that the CNSC’s self-assessment report has now become a useful reference tool for CNSC staff.</p>
68	Argentina	Article 14.2	Section 14(ii) e – Page 127	<p>The Report indicates that the licenses issued by the CNSC specify requirements for the review and approval of changes / modifications to items in the licensing basis which permit to verify that is maintained the margin of safety agreed at the time of licensing (Article 14 - Section</p>	<p>The licensing basis is described in the CNSC information document INFO-0795 <i>Licensing Basis Objective and Definition</i>. The part of the licensing basis referred-to here is “the conditions and safety and control measures described in the facility’s...licence and the documents directly referenced in that licence”. CNSC approval is required for deviations from only a small number of safety-related requirements in the licence. For example, should the licensee wish to operate the facility outside the limits of the Safety Report or the Operational Policies and Principles,</p>

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				14(ii) e – page 127). Are these requirements prescriptive or non prescriptive? Could you give an example of such verification related to a proposed modification?	this can be done only with “the prior written approval of the Commission, or of a person authorized by the Commission”. The basis for the judgement under which this approval may be given is non-prescriptive, largely because we do not expect such deviations to be requested, so any approval will be expert-based, not rule-based. The basis for judgement is provided through the RIDM process, used for example, in the Pickering B road based guaranteed shut-down state (RBGSS).
69	India	Article 14.2	14(ii)e Page 127, 18(ii) Page 155, Ap	It is stated that safety review of the NPP is carried out at the time of license renewal (i.e. at five years). The review of safety systems reliability and safety analysis report is carried out at a frequency that is higher than the plant safety review at the time of license renewal. Please explain reasons for higher frequency of review of safety systems reliability and safety analysis report, particularly when design configuration is reviewed at the time of renewal of license and also not much change in analysis methodologies / computer codes etc are expected every three years?	Regular regulatory review of the safety analysis report (currently every three years) is necessary to provide adequate oversight of analysis methodologies, computer codes, etc. The licence period for an NPP in Canada, although typically five years, has ranged from two to five years (and could exceed five years if periodic safety review is adopted). At the time of licence renewal, the safety analysis report is part of the information submitted by the applicant and is reviewed by the CNSC. However, a separate review of the updates to the safety analysis report, on a regular basis, is needed (independent of the licence application review, which could happen more or less frequently).
ARTICLE 15: RADIATION PROTECTION					
70	Germany	Article 15	Page 128, section 15 a	Are dose limits defined for the occupational exposure of trainees and students?	There are no separate limits that apply specifically to trainees and students in Canadian regulations. Occupational dose limits for Nuclear Energy Workers (NEWs) and non-

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					NEWs are prescribed in CNSC's <i>Radiation Protection Regulations</i> . A copy is available publicly at http://laws.justice.gc.ca/PDF/Regulation/S/SOR-2000-203.pdf .
71	Germany	Article 15	Page 128, section 15 a	Does Canada intend to change the dose limit for a nuclear energy worker to 20 mSv in a year, consistent with international standards such as IAEA's Safety Standards, Safety Series No. 115?	Canada has no immediate plans to change the annual dose limit for a nuclear energy worker to 20 mSv. Please note; however, that the current 5-year average exposure is 20 µSv per year.
72	Germany	Article 15	Page 131, section 15 c	What is the definition of the "members of the public with the greatest exposure"?	Members of the public with the greatest exposure refers to individuals that receive the highest doses from a particular source due to factors such as proximity to the release, dietary and behavioural habits, age and metabolism, and variations in the environment.
73	India	Article 15	15.a Page no.128 (para 3, 2nd bullet)	Section 13 of the Radiation Protection Regulations in Canada requires that every licensee ensure that the following effective dose limits are not exceeded: • 50 mSv in a year and 100 mSv over 5 years for a nuclear energy worker • 4 mSv for a pregnant nuclear energy worker for the balance of pregnancy • 1 mSv per year for a person who is not a nuclear energy worker (public) Radiation dose limit prescribed for a pregnant nuclear energy worker (4 mSv) in Canada is higher than the corresponding ICRP dose limit	<p>It should be noted that the Radiation Protection Regulations in Canada came into force in 2000 and consultation on this issue was based on the ICRP 60 recommendations.</p> <p>A dose limit of 4 mSv was adopted based on an assessment of the risks of detriment to the embryo and foetus. The following key points led to the decision to deviate from ICRP's recommendation:</p> <ul style="list-style-type: none"> - The risk to the embryo and foetus associated with a dose of 4 mSv to the mother is very small - During consultations leading to the adoption of the new limit, workers affected by it indicated that the risk implications were acceptable - Adoption of the ICRP 60 recommendation (2mSv) could lead to discrimination against women because some employers might conclude that the only effective method of compliance with the very low dose limit would be to remove a pregnant worker

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				of 1 mSv. Can Canada clarify the reasons for this?	<p>from work with radiation, or would not hire women at all.</p> <p>Extensive consultation was conducted on this topic and included 8 public meetings held across Canada to obtain worker feedback.</p>
74	Switzerland	Article 15	128	The report says that the effective dose limits for a nuclear energy worker is given with 50 mSv in a year and 100 mSv over 5 years. The international standards (ICRP 103) recommends for occupational personnel 20 mSv per year, averaged over defined periods of 5 years. Please explain why this regulation is not aligned with ICRP 103?	The dose limits defined in CNSC Radiation Protection Regulations which came into force in 2000 are based on ICRP Publication 60, published in 1991.
75	Switzerland	Article 15	128	The report says that the effective dose limit for a pregnant nuclear energy worker is 4 mSv for the balance of pregnancy. The international standards (ICRP 103) states that the working conditions of a pregnant worker, after declaration of pregnancy, should be such as to ensure that the additional dose to the embryo/fetus would not exceed about 1 mSv during the remainder of the pregnancy. Do you define the	No. The dose limit for the embryo/fetus is not defined in CNSC Radiation Protection Regulations. Refer to Question #73 for details.

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				dose limit for the embryo/fetus in the CNSC Radiation Protection Regulations? If yes, what is the dose limit?	
ARTICLE 16: EMERGENCY PREPAREDNESS					
76	Germany	Article 16.1	p. 138	Can you please comment on the different types of emergency planning zones implemented in Canada including their area?	<p>In Canada, the provincial emergency organization in consultation with the Nuclear Power Plant (NPP) Operator and the regulator will set emergency planning zones (EPZ) based on studies and research for potential severe accidents. For example, in Ontario, NPPs have a zone immediately surrounding the boundary of the nuclear installation called the "contiguous zone" and its radius is approximately 3 km. The "primary zone" has a radius of approximately 10 km and it includes the "contiguous zone". The "secondary zone" is a larger zone used to plan and prepare against possible exposure resulting from the ingestion of radioactive material. It has a radius of approximately 50 km.</p> <p>The NPPs located in the provinces of Quebec and New Brunswick have similar approaches but have determined different EPZs based on their respective studies and research.</p>
77	Ireland	Article 16.1	Page 134	As noted in the text of the Convention, each Contracting Party shall take the appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of the nuclear installation are provided with appropriate	Canada and the United States have a long history of cooperation in addressing different types of trans-boundary emergencies. Nuclear and radiological emergencies are no exception to this understanding. There is a Joint Radiological Emergency Response Plan (JRERP) in place to establish the basis for cooperative measures to deal effectively with a potential or actual peacetime radiological event in either country. The JRERP is intended to complement existing national, provincial and state emergency plans. Additional Operator involvement and sharing of information is evident especially when a nuclear

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
				<p>information for emergency planning and response. It is noted that Canada collaborates closely with the USA on emergency response plans; what types of data/information on Canadian nuclear plants has Canada shared with its neighbours to allow them to develop appropriate emergency plans?</p>	<p>facility’s emergency planning zone (EPZ) expands across the border into the neighboring state. There are organized scheduled meetings involving local, provincial and state officials as well as experts from the major nuclear facility to provide advice and updates to the existing contingency plans.</p>
	<p>Korea, Republic of</p>	<p>Article 16.1</p>	<p>Emergency Preparedness</p>	<p>Explain the evaluation system of emergency exercise 1. In case of a full scale exercise, (i.e., when off-site institutions participate in the exercise - for example, local government, regulatory bodies, emergency first responders, etc.): a. Who evaluates the regulatory body and local government? b. Is there any kind of objective evaluation criteria, including a check list? If so, explain and describe in detail. c. Are there any subjective evaluation criteria? If so, explain and describe in detail. d. Who prepares the exercise scenario?</p>	<p>Full scale exercises are usually coordinated by the Provincial Emergency Management Organization. All intervening parties from all levels of government including the Licensee will meet on a regular basis to design and develop the master scenario and events listing. The off-site evaluation component is done primarily by a team from the province.</p> <p>The CNSC has an interest in conducting its own off-site evaluation which may involve Licensee personnel. The CNSC’s main responsibility is to evaluate the Operator’s (on-site) performance during such an exercise. The CNSC evaluators follow specific guidelines or criteria that are already in place.</p> <p>As for evaluating the federal regulatory body, criteria in the form of checklists exist to assist evaluators. The criteria are based on specific prescriptive objectives which are derived from the CNSC Emergency Response Plan. Evaluators can be consultants who are hired for the job or they can be employees from within the CNSC. In either case, an after action report is produced and contains recommendations and lessons learned etc.</p>

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78	United Arab Emirates	Article 16.1	134	What is the public alerting system?	In Canada public alerting systems will vary from one Licensee to the other. Some facilities will use sirens and web based systems for informing individuals. Others will use more conventional systems such as community notification systems involving a warden service, first responders and a broadcast media for the population living in the emergency planning zones (EPZ).
79	United Arab Emirates	Article 16.1	134	Are any instructional messages sent over social mediums, such as the Internet?	Yes, the public alerting system works with automatic telephone dialing systems, cellular phones, pagers and some include email messages.
80	United Arab Emirates	Article 16.1	134	Is it possible to obtain a copy of a Provincial (i.e. Ontario) Nuclear Emergency Response and Preparedness Plan?	The Provincial Nuclear Emergency Response Plan (PNERP) is the Master Plan. It is a Cabinet (Government of Canada) approved document. It sets out the principles, concepts, organization, responsibilities, policies, functions and interrelationships to take charge of any nuclear and radiological emergencies in the Province of Ontario.
81	United States of America	Article 16.1	16,1e, p 137	(1) What is the frequency for conducting emergency exercises at the nuclear power plants? (2) How often do exercises involve other federal departments to evaluate national response?	<p>The frequency of conducting emergency exercises at the nuclear power plants is defined in CNSC regulatory document RD-353 <i>Testing the Implementation of Emergency Measures</i>, section 4.4 which states, Licensees are directly responsible for training and exercising their personnel, and for appointing qualified personnel to their emergency teams. A schedule for both emergency drills and emergency exercises should be established every year to ensure that all responders, including alternates, have the opportunity to practice the required skills on a regular basis. All emergency exercise objectives contained in Section 5 of the document should be brought into play over a five-year period, with a full scale emergency exercise every three years.</p> <p>The frequency of national exercises involving other Federal</p>

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					<p>Departments and Agencies, as listed under the Federal Nuclear Emergency Plan are set by Health Canada and Public Safety Canada and are based on risk and priorities. An exercise of a major component is normally held every two years at selected sites.</p>
82	Germany	Article 16.2	Page 139	<p>The public alerting system for NPPs in Ontario is stated to be expanded to the primary zone (10 km). What is the situation for the other NPPs?</p>	<p>In the Province of Ontario, NPPs are expanding their public alerting systems to cover their emergency primary zones of 10 km. As for NPPs in the Province of New Brunswick and Québec, their emergency primary zones are 20 km and 7 km respectively. These zone limits were based on various studies conducted for CANDU single unit stations and the actual population living in the vicinity of the plants.</p>
83	Ireland	Article 16.2	Page 140	<p>The report notes that ratification of the Assistance Convention is pending a review of domestic implementing legislation; when is it anticipated that this review will be completed?</p>	<p>The Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency was signed by Canada in December 1986 and subsequently ratified by Parliament in August 2002.</p>
ARTICLE 17: SITING					
84	Germany	Article 17.1	17(i), Page 145; 17 (iii), Page 148	<p>In the draft guide for the application for a license to prepare a site (c.f. 17 (i)) as well as in the framework of reevaluations (c.f. 17 (iii) a)) the consideration of climate change effects is mentioned. Is there a sound scientific basis (i.e. data and methods) for a quantitative assessment of climate change effects on the frequency and intensity of rare events?</p>	<p>The effects of climate change on the frequency and intensity of extreme events have been widely recognized, and they have been undergoing extensive studies world-wide. There are still considerable uncertainties on the results and methodologies. Nevertheless in engineering practice, they have been taken into account through the use of additional safety margins in important designs. CNSC considers it necessary and practical to have a bounding analysis of the climate change effects in the new builds designs.</p> <p>The assessment of climate change, for example as performed for the New Nuclear Project at Darlington, uses climate change predictions that have been developed by</p>

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					<p>Environment Canada, the International Panel on Climate Change, and Natural Resources Canada. The studies referenced include historical information as well as predictions of continuing future trends in the specific area being assessed; the Great Lakes Basin.</p> <p>The predictions provided in these studies are used to bound the climate change effects such that a qualitative assessment can be performed in accordance with the applicable guidance developed for such assessments. The bounding predicted values that represent the expected change are compared to the design values to identify whether a bounding value would warrant a change in the design. Event based values representing a potential safety impact for consideration in design, for example wind speed events under climate change, are compared to the value used in the design process. Generally, the conservative nature of the values used in design address the concerns arising from climate change. Non-event based values, for example representing surface water temperature, are considered for process performance impacts, and again the bounding values are used for the assessment.</p> <p>OPG is committed to an adaptive management strategy to manage any variability in the environment over the life of the project, integrating design, management and monitoring to learn and adapt as necessary to the effects of climate change.</p>
85	India	Article 17.1	Page 142-143	Level of NPP Design Information Expected to Demonstrate Site Suitability: In Canada, the EA process and the consideration of an application for a licence to	In the case of the EA and application for a licence to prepare site for a new NPP at the Darlington site, the approach taken by OPG was to derive two source terms based on the CNSC safety goals for both the Small Release Frequency (SRF) and Large Release Frequency (LRF), as specified in RD-337 <i>Design of New Nuclear Power Plants</i> .

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				<p>prepare a site for a new NPP in Canada do not require a proponent to select a specific design. However, the consequences of postulated accident in the selected design type should be within the approved EA. In view of this information i) How source term is selected for EA, particularly when it is also stated that for this assessment accidents having frequency upto 10⁻⁰⁶ per year are considered, which is design specific? ii) Up to what distance EA is carried out as part of license for site</p>	<p>Such Safety Goal Based (SGB) releases are expected to bound the releases from any credible accidents (i.e., within 10⁻⁶/yr) for any of the reactor designs considered, should they become licensed in Canada.</p> <p>A core radionuclide inventory was selected from one of the reactor technologies considered, based on factors such as maximum reactor core size and maximum fuel burnup rate. A baseline release, the amounts of each radioisotope released, was then determined based on the release fractions associated with a selected accident scenario from the safety analysis of that reactor design (a severe accident involving damage to the reactor fuel, that was a high contributor to the large release frequency).</p> <p>The SGB releases were then derived by adjusting the baseline release using scaling factors to reflect the RD-337 SRF and LRF threshold release values, as follows:</p> <p>Case 1: The I-131 in the baseline release was scaled to the RD-337 SRF threshold value of 1x10¹⁵ Bq. The same scaling factor was then applied to each radionuclide in the baseline release.</p> <p>Case 2: The Cs-137 in the baseline release was scaled to the RD-337 LRF threshold value of 1x10¹⁴ Bq. The same scaling factor was then applied to each radionuclide in the baseline release.</p> <p>These stylized RD-337 SGB releases to the environment were used in dose calculations. In this context, the distances considered in the EA include the 0-10 km Primary Zone area around the new NPP for which detailed planning and preparedness for exposure control measures would be</p>

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86	India	Article 17.1	17(i), Page 145	<p>In RD 346 and as part of license for site i) What are the return periods considered for severe weather/ flood/ wind for deciding site grade elevation?</p> <p>ii) Are there any guidelines for accounting for climate change during the design life/ extended operation?</p>	<p>expected to be conducted.</p> <p>For severe weather, flood or wind the return periods are not prescribed; however, the applicant is expected to propose adequate periods based on criteria identified in IAEA documents referenced in RD-346 <i>Site Evaluation for New Nuclear Power Plants</i>, for example Safety Guide No NS-G-3.4 and Safety Standards NS-G-1.5, NS-G-3.2, NS-G-3.4, NS-G-3.5.</p> <p>For new builds, the environmental assessment performed at the beginning of the project requires the proponent to consider climate change in areas such as external events, and effects of the plant on the environment over the projected lifespan of the project. The request by a licensee to undertake a plant life extension project triggers an environmental process which will examine the potential environmental impacts of the undertaking. The effects of climate change on the extended life are generally examined as part of the process and would be reflected in the Integrated Safety Review case put forward by the licensee in their licensing proposal.</p>
87	Korea, Republic of	Article 17.1	p.145	<p>In Section “17 (i) Evaluation of Site-Related Factors”, it is stated that flight paths for major airports could be one of the review items to check possibility of airplane crashes. Do you have any regulatory requirements considering the intentional aircraft impact to NPPs after the 9/11 attack? If yes, what is the detailed regulatory requirements for the intentional aircraft impact?</p>	<p>Intentional or unintentional aircraft crash is not explicitly prescribed in Canadian regulations; however, for new build expectations are described in two regulatory documents:</p> <ul style="list-style-type: none"> - RD-346 guides a proponent to perform a Site Selection Threat Risk Assessment which, as part of the investigation, examines threats due to aircraft. This information would feed into the site suitability decision as well as the plant design process. - RD-337 requires an proponent to ensure the design considers all natural and human-induced external events that may be linked with significant

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					radiological risk. This includes potential aircraft crashes, intentional or accidental.
88	United Arab Emirates	Article 17.1	142	Based on Canada’s CNS National Report, it is understood that site evaluation in Canada is a regulated activity and is conducted using NPP bounding design parameters to assess environmental impacts and site suitability and to determine a site envelop to which a range of reactor designs can be compared. Since the reactor design of choice in Canada is the CANDU design, can the value of using the bounding approach for siting ever be realized? Is Canada considering using a non-CANDU reactor technology?	For new NPPs in Canada, the reactor designs considered are not limited to CANDUs. For instance, in its Environmental Assessment (EA) and Application for a License to Prepare Site for a new NPP at Darlington, OPG has followed a multi-technology approach in considering various reactor technologies, including non-CANDU designs. Specifically, for the proposed Darlington new NPP, a Plant Parameter Envelope (PPE) approach has been followed (similar to the US-based PPE approach) encompassing the following reactor designs: the AP1000 by Westinghouse; EPR by Areva; ACR-1000 by AECL; and the Enhanced CANDU-6 by AECL. This PPE has been used as part of a bounding framework for the EA and site evaluation studies of the proposed Darlington new NPP. Given the variety of reactor technologies taken into consideration, the value of the bounding approach has indeed been realized through the robustness of the performed EA and site evaluation studies.
89	United Arab Emirates	Article 17.1	142	With respect to the application for a licence to prepare the site for a new-build project proposed for the Darlington site in Ontario, it would appear that the new reactor’s location would be evaluated against the identical parameters used for the site envelop to locate existing reactors at that same site. Could this site preparation license be granted more or less	The new build site next to the existing Darlington site is considered to be a separate site per RD-346. As a result, CNSC conducts its reviews of the EA, EIS and license application anew for the new build plant. However, the applicant has the advantage of existing data as well as any new data from investigations of the site and the surrounding region. This data is used to support the applicant’s licensing case for the Licence to Prepare Site and in the Environmental Impact Statement where the applicant demonstrates it meets the Environmental Impact Statement Guidelines specific to the project.

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				by inspection, since it would be a similar reactor design at the same site; only with the addition of one more source term? or would CNSC conduct its reviews of the EA, EIS and license application anew?	
90	China	Article 17.2	14.(ú@), 114	What considerations have been made regarding public participation during NPP siting?	<p>The Nuclear Safety and Control Act (NSCA) requires that before the Commission makes a licensing decision, it must give the applicant / licensee an “opportunity to be heard”. In the interest of fair play, the Commission must give the person most affected by the decision the opportunity to present their views to it before making its decision. With respect to certain decisions made by the Commission, the NSCA imposes an added obligation to hold a “public hearing”. Before making a licensing decision under subsection 24(2) (major nuclear facilities, including NPP siting, construction and operation) or where it would be in the public interest to do so, the Commission must hold a public hearing. A public hearing is a hearing structured so as to give affected parties and in most cases interested members of the public a reasonable opportunity to make submissions in relation to the matter to be decided by the Commission. Public hearings are a highly visible component of the work of the Commission.</p> <p>The CNSC Rules of Procedure facilitate and encourage active participation by members of the public. In addition to notifying the applicant or licensee, the Commission gives 60 days advance notice of a public hearing in a manner which is likely to come to the attention of interested members of the public. As a general rule, the notice of public hearing is posted on the CNSC website and is also published in newspapers serving the area in which the</p>

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					<p>facility is located. The notice supplies information on the duration of the hearing (one or two days), its purpose, dates, time, place and the deadlines for filing documents prior to the hearing.</p> <p>Participants may attend in person to make their presentations or have their written submissions considered in a public forum. Members of the public may also attend and observe the proceedings without further formality. In order to participate actively in the hearing, interested persons must seek and be granted the status of an intervenor by the Commission. Public hearings are usually well attended by members of the public and of the media, and may include a number of intervenors (e.g., individuals, unions, employees, community and environmental groups). The Commission has a public hearing room in Ottawa but may from time to time conduct hearings at different locations across the country, to provide a greater opportunity for the public to participate in or observe its proceedings. The Commission allows the use of teleconferencing and videoconferencing to facilitate public participation, and video Webcast all its public hearings and meetings so that all interested persons can view the proceedings from anywhere in the world.</p> <p>The Commission Members rely on written submissions, hear oral presentations based on those submissions, and ask questions to complete the evidence and argumentation pertaining to each matter. The applicant and any intervenors may question each other and any witnesses, but only with the permission of the Commission and in the manner that the Commission may determine. Questioning is controlled by the Commission through the presiding Member. The guiding principle, which is stated in the</p>

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					<p>NSCA, is that all proceedings before the Commission shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.</p> <p>With respect to the upcoming Darlington NPP New Build Site Preparation project, in addition to the above, the public was provided real-time access on the Web to all the documents filed as well as provided an opportunity to comment – pre-hearing – on all the filed submissions. Furthermore, a special public information session was held and webcasted so that outstanding issues could be discussed in a public forum, again prior to the conduct of the public hearing. Another special feature of the upcoming NPP siting hearing is that, to further encourage public participation, members of the public will be provided, at the end of each hearing day, the opportunity to take a few minutes to make their views known, even though they did not register as intervenors and have not filed written submissions.</p>
91	India	Article 17.2	17(ii) Para 3, Pg 146 and Annex 17(iii)	Fish Impingement and Entrainment: Was there any change in the environmental requirement for the site or in the environment itself which called for the introduction of barrier to reduce fish impingement in 2009?	The issue was raised during the Environmental Assessment for the proposed refurbishment of Pickering B. The Department of Fisheries and Oceans noted concerns with the scale of impingement/entrainment losses of fish at Pickering and that they had been in dialogue with OPG since 2003 on this issue.
ARTICLE 18: DESIGN AND CONSTRUCTION					
92	Argentina	Article 18.1	Section 18 (i) – Page 154	It is showed some important examples of design changes in the currently operating NPPs to enhance defence-in-depth (Article 18 - section 18 (i) – page 154) among which a	The limiting conditions for sheath dry-out in the current 37 Element fuel bundle design occur on the portions of the inner ring element sheaths that border the sub channels between those elements and the centre element. Reducing the diameter of the centre element increases the cross-sectional area of those sub-channels and preferentially

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				modification of the 37-element fuel bundle design is mentioned. Please, could you give us more details of the reasons and the features of this modification?	<p>increases coolant flow past the inner surfaces of the inner ring element sheaths. This small change in bundle geometry results in a more balanced distribution of dry-out margins throughout the modified fuel bundle elements and increases the dry-out power of the modified bundle when compared to the current design.</p> <p>This improved performance of the modified 37 Element fuel bundle will offset the gradual reduction in fuel bundle sub-channel flow as the fuel channel pressure tubes creep radially during operation.</p>
93	China	Article 18.1	18, 151	OPG submitted its application for constructing new power plant, what progresses have the safety systems in new CANDU reactor made in respect to diversity, redundancy, physical isolation and single failure criteria?	<p>The Enhanced CANDU 6 (EC6) is an evolution from the CANDU 6 reference design (Qinshan). For a Canadian location, the Qinshan design requires specific design changes to meet current Canadian licensing expectations, notably RD-337 <i>Design of New Nuclear Power Plant</i> and RD-310 <i>Safety Analysis for Nuclear Power Plant</i>. In particular this will affect the design by the addition of a new safety system (Emergency Heat Removal System), addressing the “new” requirements for Safety goals, Severe Accidents, Single Failure Criterion, System Classification, Containment Design and Malevolent Acts and Seismic frequency of occurrence.</p> <p>Safety systems are subject to and will meet the “regulatory” requirements as specified in RD-337 and RD-310 to address diversity, redundancy, physical isolation and single failure criteria.</p>
94	India	Article 18.1	Page 152	Vendor Pre-Project Design Reviews : Pre project design review is a good practice established by CNSC. Phase-2 of the pre project design review calls for compliance to	<p>The following 16 topical areas are usually covered in Phase-2 of a pre-project design review:</p> <ul style="list-style-type: none"> • Defence in depth, SSC classification, dose acceptance criteria • Reactor core nuclear design

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				<p>RD-337 and other documents. Please provide, the 16 specific topical areas covered and how do they cover the content and intent of RD-337 and other documents. What are the typical time frames for each phase of review?</p>	<ul style="list-style-type: none"> • Means of shutdown • Fuel design • ECCS and emergency feedwater system • Reactor control system • Containment • Pressure-boundary design provisions for the PHTS • Severe Accident prevention and mitigation • Fire protection • Radiation protection • QA program • Human factors • Out-of-core criticality • Robustness, safeguards and security • Safety analysis <p>A 17th topic (R&D program) may be added if warranted. Generally, these topics cover the content and intent of the RD-337 document. The durations of the individual phases of pre-project reviews vary, but, typically, Phase 1 takes 6 to 9 months and Phase 2 may take 12 to 15 months. The duration of Phase 3 is dependent on specific vendor requests.</p>
95	Romania	Article 18.1	Page 151	<p>Could you please provide some information on the basis for the establishment of the dose acceptance criteria and quantitative safety goals set in the CNSC Regulatory Document RD-337, Design of New Nuclear Power Plants?</p>	<p>In general terms, the dose acceptance criteria in RD-337 follow from the postulate that the risks due to a new technology should not be significant contributors to the already existing societal risks. The dose acceptance criteria must also be sufficient to ensure that very few accidents will require protective measures.</p> <p>The Large Release Frequency safety goal is expressed in terms of the release of Cs137 that would require long-term relocation of population to mitigate health effects. The Small Release Frequency safety goal is in turn expressed in</p>

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					terms of the I131 release that would require temporary evacuation to mitigate health effects. To achieve a balance between prevention and mitigation, a third goal is defined to limit the frequency of Severe Core Damage. This ensures that the designer does not place too much reliance on the reactor containment.
96	United States of America	Article 18.1	18, p 152	The report references an optional process for vendors to obtain CNSC pre-project design reviews and states that the conclusions of these reviews are non-binding and typically provided to the vendor in a confidential report. How often is this optional process used?	<p>Since inception of the optional pre-project design review process for vendors, two have taken advantage of the process:</p> <p>Atomic Energy of Canada Limited (AECL)</p> <ul style="list-style-type: none"> • the ACR-1000 completed Phase 1, 2, and 3 as of January 2011 • the EC-6 design completed Phase 1 in March 2010 and Phase 2 is currently in progress <p>Westinghouse, the AP-1000 design completed Phase 1 in February 2010.</p> <p>Other reactor vendors requested additional information in 2010 from CNSC staff about the process and are considering pursuing a Phase 1 review in 2011.</p>
97	Argentina	Article 18.2	Section 18 (ii) – Page 155	Related to the criteria and provisions for incorporation of proven technologies in existing NPPs (Article 18 - section 18 (ii) – page 155) it is mentioned that the CANDU design criteria and requirements include design and construction of all components, systems and structures to follow the best	<p>An example where the design and construction of all components, systems and structures follow a best applicable code or standard is the pressure-retaining systems and components standard, CSA N285.0 <i>General requirements for pressure-retaining systems and components in CANDU nuclear power plants</i>. The Canadian regulatory practice is as follows:</p> <ol style="list-style-type: none"> 1. The licensee or an agent of the licensee prepares the design of a pressure-retaining system, structure or component, and proposes a code classification in

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				<p>applicable code, standard or practice and be confirmed by a system of independent audit. Could you give us information about the system of independent audit utilized?</p>	<p>accordance with the rules in CSA N285.0.</p> <ol style="list-style-type: none"> 2. The licensee submits an application to the CNSC to obtain approval of the code classification. 3. CNSC staff reviews that application and the design information submitted in support of the application, and if deemed to meet the requirements in the <i>Nuclear Safety and Control Act</i> and its Regulations, approves the code classification for the system, structure or component. 4. The licensee then submits a design registration package to an Authorized Inspection Agency to register the system, structure or component in accordance with CSA N285.0. The Authorized Inspection Agency is an organization designated by the CNSC as authorized to register designs and procedures, perform inspections, and perform other defined functions. 5. During fabrication of pressure-retaining structures or components, an Authorized Inspector employed by an Authorized Inspection Agency conducts audits of the fabricator. 6. During construction of pressure-retaining structures or components, an Authorized Inspector employed by an Authorized Inspection Agency conducts audits and inspections of the construction. The Authorized Inspector accepts the inspection and test plan, and then inspects and countersigns the data reports for pressure tests. <p>For tools and methodologies used in the safety report, the</p>

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					CNSC expects that the computer programs have been validated in accordance with CSA N286.7 <i>Quality Assurance of Analytical, Scientific and Design Computer Programs for Nuclear Power Plants</i> . CNSC staff reviews the submissions from the licensees, and conducts compliance verification activities, i.e., inspections and audits, on the licensee’s implementation of CSA N286.7.
98	Argentina	Article 18.2	Section 18 (ii) – Page 156	The report says that an adequate qualification program is established to verify that the new design meets all applicable safety expectations (Article 18 - section 18 (ii) – page 156). Could you provide information about the content and features of the qualification program used?	The qualification program used is non-prescriptive in nature; and depends on the SSC being addressed. In view of the CNSC’s performance-based approach, the applicant does have to demonstrate that the SSC will meet the requirements of RD-337 <i>Design for New Nuclear Plants</i> , and the expectations listed in RD/GD-369 <i>Licence Application Guide: Licence to Construct a Nuclear Power Plant</i> for the SSC.
99	Belgium	Article 18.3	E, 15	Which kind of question should be submitted?	No response required. Not a question.
ARTICLE 19: OPERATION					
100	United Kingdom	Article 19.1	Page 160	Your report on the regulatory oversight of the commissioning activity mentions Commissioning control points (CCPs), non-licensing CCPs and licensing CCPs.. The distinction is not clear, can Canada please expand? Canada is requested to provide more detail on the following; - at a CCP, is a review of the test results completed before continuing? If so, does the review enable a	<p>Licensing commissioning control points are regulatory hold points, requiring prior authorization by the Commission or a person authorized by the Commission to proceed further in the commissioning program.</p> <p>Non-licensing CCPs are CNSC witness points, as observed by CNSC staff.</p> <p>All applicable non-licensing CCPs must be satisfactorily completed as part of obtaining the release from licensing CCPs. Plant management is expected to have appropriate control of all CCPs.</p> <p>Test results are reviewed by the CNSC prior to release of</p>

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				<p>judgement to be made on whether the commissioning programme should continue, and whether the succeeding stages should be modified as a consequence of the test results or because some tests in the stage had not been undertaken or had not been completed? - Are commissioning tests designed to be of sufficient duration to allow the systems and components under test to reach their normal equilibrium conditions, and provide enough duty hours to reduce the probability of failure in the early stages of operation? Please provide a description of the management structure for commissioning. Please provide more information on regulatory oversight of each of the above features.</p>	<p>the CCPs and proceeding with the commissioning program.</p> <p>The review does enable a judgement to be made on whether the commissioning program should continue. The CNSC may request modification to succeeding stages as a consequence of the test results.</p> <p>It is the responsibility of the licensee to submit a comprehensive commissioning program that defines the tests to be performed, complete with acceptance criteria. CNSC staff assesses compliance with the licensee’s program, taking into consideration the characteristics to be inspected or tested, as well as the relevance of the tests to the proposed operational limits and conditions. The CNSC will have site inspectors present at the facility and subject matter experts as appropriate.</p> <p>Following the suspension of the Darlington New Build project in June 2009, the management structure for commissioning was disbanded. As a result, plans have not yet been established for detailed commissioning activities for the new build project.</p> <p>The role of the CNSC is to review and assess selected commissioning activities performed by the licensee and ensure they meet defined acceptance criteria as well as all pertinent regulatory and licensing requirements. Existing governance requires the development of detailed commissioning specifications to demonstrate that applicable design, licensing and operational requirements are met.</p>
101	China	Article 19.2	19.(ii), 161	What is the essential difference between the limited condition of operation determined by	The SOE defines a complete and comprehensive set of limits derived from the Safety Analysis through controlled processes, while the OP&P present only a subset of those

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				safe operating envelope project and the specifications in the OP&P being used presently? Will the limited condition of operation values have a great many modifications after the safe operating envelope project?	limits. For stations that are far advanced with their SOE projects, the SOE limits have been checked against OP&P limits. Only minor discrepancies have been found to date. Full implementation of the SOE project is not expected to lead to significant changes to limits that are currently listed in the OP&P.
102	India	Article 19.4	19(iv) Pg 166,167, Annex 19(iv) Pg 271	With regard to the plant specific SAMGs, it is mentioned (Page-166) that ‘The measures to be implemented differ somewhat depending on the location and nature of NPP’. Please explain the aspects of SAMGs considered which depend on location of NPP?	In Canada, all organizational aspects and criteria for implementation of off-site protection measures for population in the vicinity of a NPP fall within the responsibilities of the local authorities (i.e., the Provincial government) and differ from one Province to another. The differences in the type of criteria triggering off-site protection measures may induce differences in the data acquisition (i.e. measurements) and processing (i.e. computational aids) in SAM. These differences are reflected in the communications between the plant-specific SAM organization and the authorities responsible for the off-site management of the emergency.
103	India	Article 19.4	Annex 19(iv) Page 272	It is mentioned that implementation of key elements of SAMG programme is in process for Bruce-A, which involves ‘minor design changes’ also. It is also mentioned that a validation exercise is completed in 2009. Please explain i) What was the scope of this validation exercise? ii) What is the acceptance criteria put forth by CNSC for these validation exercises? iii) What	The scope of the validation exercise, conducted in 2009, was the response to a major simulated event which will require entry into the Bruce Power Severe Accident Management Guides (SAMG). Involvement was limited to those Site Management Centre members including the Technical Support and MCR / EOC who would be directly involved in SAMG only. Other emergency response groups and contacts, including some SMC members, were simulated or role-played as necessary to support the exercise. The scenarios and extents of play were designed to allow actual or simulated demonstration of activities supporting the SAMG. There were no CNSC acceptance criteria for this validation

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				design changes were involved in implementing the SAMGs?	<p>exercise; however, the exercise was designed to meet CNSC expectations as defined in CNSC Regulatory Guide G-306 <i>Severe Accident Management Programs for Nuclear Reactors</i>.</p> <p>The design changes involved in implementing SAMG, for Bruce A, include the installation of an Emergency Moderator Make-up System, the installation of Passive Auto-catalytic Recombiners in containment, the installation of additional environmentally qualified hydrogen igniters in containment, modifications to the ECC sump level transmitter, a ventilation box-up modification outside of containment and the design of 16 alternative strategies for adding water into the heat transport and moderator systems (these are designed as temporary changes that would only be installed in the event of a severe accident).</p>
104	Pakistan	Article 19.4	Annex 19 (iv),Page 271	Are the SAMGs at different NPPs supplemented with deterministic severe accident analyses?	<p>Deterministic severe accident analyses are assisting the licensee in areas such as development of computational aids and procedures for SAM, identification of potential strategies for mitigation of consequences of severe accidents, training, conducting validation exercises, etc. However, during an emergency, the symptom-based approach is used based on the observed plant parameters. Reliance on detailed analyses is minimized and capability of performing deterministic severe accident analyses is not needed.</p>
105	Korea, Republic of	Article 19.6	p.50 & p.169	It is stated (in page 50, 169) that CNSC staff members assess the significance of all events or situations that are outside the normal operations described in the licensing basis, and the significance is determined using operational	<p>Events of low safety significance are usually “reviewed” and “tracked” to ensure the licensee cause identification and corrective actions are appropriate and completed in accordance with regulatory requirements.</p> <p>Events of higher safety significance may be investigated by Regulatory Staff to independently confirm the event causes and required corrective actions. Procedural guidance on the</p>

Ser	Country	Original Reference	Reference in Report	Question/Comment	Response
				<p>procedures or expert judgement. Please explain the difference in the regulatory activities according to the significance of events.</p>	<p>type of events which should be investigated independently by Regulatory Staff is available. Procedural guidance on the conduct of the different types of regulatory investigations is also available. The methodology used by Regulatory Staff during the conduct of these regulatory investigations is based on TapRoot®, a patented individual and enterprise software designed to streamline and organize the incident investigation.</p>
106	Germany	Article 19.7	Page 167	<p>After the event in the NPP Pickering of August 2003 a new auxiliary power system was installed. Do the other Canadian NPPs have such a power station or are there any retrofit measures? Are there Canadian requirements with regard to auxiliary power systems?</p>	<p>A major difference between Pickering B and other NPPs in Canada was that Pickering B could not be cooled down without Class IV power (i.e. the Class III service water system could not provide sufficient cooling water to the shutdown cooling system to cool down the reactor). The new Auxiliary Power Supply that was installed has sufficient power to run the Class IV service water pumps to allow cool down of the reactor in event of a loss of grid. At all other NPPs in Canada, the reactors can be cooled down using Class III power so there is no need for an APS.</p>
107	Pakistan	Article 19.7	Appendix E.2, Page 184	<p>Does the Canadian industry follow the concept of sustained steam flow “critical/trace flow” for hydrogen production assessment in case of LOCA with loss of ECCS?</p>	<p>Canadian plants that are undergoing or planning refurbishment must comply with RD-337 to the extent practicable. In LOCA and LOECCS with a trace flow, the hydrogen and radio-nuclide source terms experience step increases and thus represent a specific challenge to the containment function. The accident needs therefore to be addressed in the design of the containment mitigating measures. However, in the framework of RD-337, this accident could be classified as a Beyond Design Basis Accident (BDBA) and realistic analysis and relaxed design rules could be applied.</p> <p>For plants that will not be refurbished, the regulatory document R-7 serves a basis for containment requirements and, according to R-7, a bounding LOCA and LOECCS is to be considered.</p>

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108	France	Article 19.8	§2 - p171	"Could Canada provide details about the management of high level radioactive waste produced by NPPs? Are the waste stored on site like other nuclear waste or have dedicated interim storages?"	<p>In Canada, all spent fuel (high-level waste) from nuclear power plants is stored in interim storage at the site where it was produced. When the fuel first exits a power reactor, it is placed in water-filled bays. Water cools the fuel and shields the radiation. After several years in the bays – six to 10 years, depending on site-specific needs and organizational administrative controls – and when the associated heat generation has diminished, the spent fuel can be transferred to an onsite interim dry storage facility.</p> <p>Further information on Canada’s provisions for the interim storage of spent fuel from nuclear power plants can be found in the Third Canadian National Report for the <i>Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management</i>, published in October 2008. This report is available on the CNSC and IAEA Web sites.</p>
109	France	Article 19.8	§2 - p171	"Could Canada give more details about methods used for conditioning radioactive waste? Does Canada use other kind of treatment other than incineration before conditioning radioactive waste?"	<p>Compaction is a method that may also be used. Further information on ways that Canada minimizes low- and intermediate-level radioactive waste from nuclear power plants can be found in the Third Canadian National Report for the <i>Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management</i>, published in October 2008. This report is available on the CNSC and IAEA Web sites.</p>
110	France	Article 19.8	§3 - p 171	Could Canada indicate which long term routes are foreseen for LLW and ILW, other than interim storages?	<p>Ontario Power Generation (OPG) is proposing the construction of a deep rock vault in clay-rich limestone, hundreds of metres below ground. This Deep Geologic Repository (DGR) will be a long-term management facility for OPG’s low- and intermediate-level radioactive wastes. The proposed location for the DGR is the Bruce nuclear site in Tiverton, Ontario (Municipality of Kincardine). In June 2007, the Minister of the Environment referred the DGR project environmental assessment to a review panel and it is</p>

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					<p>expected that the appointment of the joint review panel (JRP) will be announced in January 2011. The JRP will assess the environmental assessment and the first stages of licensing.</p> <p>More information about this project is available at www.opg.com and the Nuclear Waste Management Organization (www.nwmo.ca) who is seeking regulatory approval, on behalf of OPG, for the construction of a DGR</p>