



September 21, 2018

Re: Comments on CNSC’s Draft REGDOC-1.1.5

CNSC’s efforts in providing SMR proponents with additional guidance to assist them in their preparation for licence applications is welcomed. The opportunity to provide comments on the draft document REGDOC-1.1.5, “Licence Application Guide: Small Modular Reactor Facilities”, July 2018, is also appreciated.

The draft document REGDOC-1.1.5 is useful in providing to prospective licence applicants suggested topics under each of the 14 safety and control areas for which emphasis should be considered in their licence application submissions, from a risk-informed perspective and with consideration for specific characteristics of most SMR designs. The document is also useful to prospective applicants for better preparing for pre-licensing engagement with the CNSC staff. The document could benefit of some additional clarity in a few areas. Hopefully, the comments provided in the table below may assist CNSC staff in that respect.

Sincerely,

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#	Section#/ Paragraph#/ sentence or bullet#/ page#	Relevant excerpt from the Draft REGDOC-1.1.5 (July 2018), as applicable	Comment
1	1.1 / 2 / 2 / 1	“RD/GD-369, ... Licence to Construct a...”	Although not directly a comment on this document, it would be of interest to know if RD/GD-369 will be replaced with an upcoming REGDOC-1.1.2. If so, when would the target date for its draft be?
2	1.1 / 3 / 1 / 1	“...(for example, when determining site suitability...”	The information in brackets is not clear. If by “site suitability” it is meant site <i>selection</i> , the site selection process is outside the formal licensing process and it is not regulated under the NSCA (per Section 3 of REGDOC-1.1.1). If it is meant suitability as a result of site <i>evaluation</i> , the site evaluation process can be initiated before a Licence to Prepare Site (LTPS) application is submitted to CNSC, and can/would continue after such application is submitted. The former case is outside formal licensing, thus the need for an environmental assessment (EA) would formally not be identified at that stage. For the latter case, when the application has been already submitted,

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			the need for an EA would be determined shortly after the applicant's submission (but would likely be before the site evaluation would be completed); in this case it is not clear where site suitability comes into play when identifying the need for an EA.
3	1.2 / item 1/ last sentence / bottom page 1	"...and takes place before a proponent would submit a licence application..."	For an LTPS "licence application", a VDR can also take place in parallel with the already initiated LTPS review by CNSC. This could be the case because a VDR focuses on the design of the facility and on the vendor, while the LTPS focusses on the site aspects of the project (e.g., site evaluation, preparation, environmental protection, etc.) and on the licensee/applicant. It is expected that the VDR will cover in much more depth the design aspects than the information required in support of an LTPS application would contain. Thus, a vendor may decide to engage in the VDR process <i>in parallel</i> with the LTPS activities, and probably before a Licence to <i>Construct</i> (LTC) application is submitted.
4	1.2 / item 2/ 1 st sentence / top of page 2	"Pre-licensing engagement"	It is not clear from this document if this "Pre-licensing engagement" is an optional process or a mandatory one, although it may be inferred that it is optional (see also next comment).
5	1.2 / item 2/ 1 st sentence / top of page 2	"Pre-licensing engagement"	Related to above comment: is this "pre-licensing engagement" process the same with the one that is mentioned in Section 3.2.2 of REGDOC-2.9.1, "Environmental Principles, Assessments and Protection Measures", December 2016? If so, maybe a reference to that REGDOC-2.9.1 could be provided, for clarity. If not, what are the differences? It is also noted in Section 3.2.2 of REGDOC-2.9.1 that the applicants "...are encouraged to seek CNSC guidance...", which means that the pre-licensing engagement (if it is the same process that is referred to in both REGDOC-2.9.1 and 1.1.5) is not mandatory.
6	1.2 / item 2/ 2 nd bullet / top of page 2	"Offer guidance on preparing a licence application for submission to CNSC."	It is assumed that such guidance offered by CNSC staff will be in addition to the information already contained in REGDOCs -1.1.1, -1.1.3, -1.1.5 (this document), and RD/GD-369, rather than a repeat of the information contained in those documents. For example, guidance with respect to applicability of

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			other Federal and/or Provincial Acts, regulations and requirements, other than those under NSCA and EA.
7	2.2 / 3 / 3 rd / 3	“Sections 2.2.1–2.2.14 provide SCA-specific information that a proponent should consider when determining the extent of the emphasis to give each SCA in a licence application.”	From this statement it could be inferred that, from a risk informed perspective, other “considerations” that are not mentioned in these sections could be de-emphasized. If that is not the case, it could mean that CNSC’s expectations for SMRs may be exceeding their expectations for “traditional” NPPs. A clarification would be useful.
8	2.2.1 / 4 / item 6 / 4	“6. Extent and need for critical human involvement in the activities of the facility.”	Emphasis should also be on the consideration for the frequency of such activities. (not only extent and need)
9	2.2.2 / 5 / item 5 / 5	“5. Extent and need of critical human involvement in the activities of the facility.”	Emphasis should also be on the consideration for the frequency of such activities. (not only extent and need)
10	2.2.3 / 4 / item 2 / 6	“2. type of activities to be performed”	Emphasis should also be on the consideration for the frequency of the activities to be performed. (not only type)
11	2.2.4 / 4 / item 1 / 6	“1. The number of provisions in the design to reduce risk.”	This seems to imply that the higher the number, the better the risk reduction is. It puts an emphasis on the number of design provisions rather than on the effectiveness and quality/robustness of the design provisions. Same comment is applicable to sections 2.2.5 through 2.2.7.
12	2.2.4 / 4 / item 4 / 6	“4. The number of passive safety systems.”	Similar to the previous comment (see above), this may imply that the higher the number of passive safety systems the more concerns may be. A better statement would be “The number of passive safety systems <i>vs. the number of active safety systems</i> ”; in other words, the more use or reliance on passive safety systems instead of active safety systems, the better it should be.
13	2.2.4 / 4 / item 11 / bottom of page 6	“Ability to manage change in facility design and/or operation...”	This seems rather an aspect of management system than safety analysis. It is already understood that an acceptable management system is expected to be applied throughout the SCAs.
14	2.2.4 / 5 / all / 7		The list of considerations should also include inherently safe design characteristics, as well as potential emphasis in design on Level 1 Defence-in-depth (DiD) vs the other DiD levels. On the latter aspect, the better the Level 1 DiD SSCs do their job in

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			preventing releases, the less emphasis / reliance should be expected on the other levels of DiD to mitigate releases.
15	2.2.13 / 4 / item 2 / 12	“2. Measures taken to report, contain, verify and provide other information required by Canada’s international obligations”	It is not clear how this consideration would be different for an SMR from a “traditional” NPP. A better consideration could be ease or difficulty of access to nuclear material on site.
16	A.1 / 6 / item 1 / 15	“1. Meet regulatory requirements”	Alternatives may be proposed because some of the existing requirements (as currently written to reflect water-cooled reactor designs, as it is also specified at the beginning of Appendix A of the draft REGDOC-1.1.5) may not apply to certain SMRs’ design characteristics, thus may not be applicable. So one would already <i>not</i> expect such regulatory requirements to be met. It is suggested the wording be changed to “Meet <i>applicable</i> regulatory requirements”, or “Meet regulatory requirements <i>or their underlying safety principles</i> ”, or “Meet regulatory requirements <i>or their intent</i> ”. Same comment for the bullet “Regulatory requirements have been met”, located a few paragraphs below, in the same section A.1.
17	A.1 / entire paragraph 9 / page 15	<p>“When the CNSC assesses applications that use a graded approach, its primary consideration is to ensure that risk is demonstrated to be at a reasonable level. This includes ensuring that:</p> <ul style="list-style-type: none"> • Regulatory requirements have been met • Fundamental safety functions have been met • Defence in depth is demonstrated • Safety margins are appropriate and in line with specific hazards over the facility’s lifecycle” 	The information/text in this paragraph seems to be redundant with some of the paragraphs that appear before, in the same section A.1.

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18	A.1 / 10 / page 15	“Existing expectations provide...”	It is not clear what “existing expectations” means. Is it existing regulatory requirements, or CNSC staff expectations (e.g., potentially unwritten expectations), or...?
19	A.2 / 1 / item 3 / top of page 16	“3. The application of one or more CNSC requirement(s) would not serve the underlying purpose of the requirement(s) or is not necessary to achieve the underlying purpose of the requirement(s).”	Instead of “the underlying purpose of the requirements(s)”, it may be more appropriate to say, “the underlying <i>safety principle(s)</i> that the requirement(s) reflect”.
20	A.2 / 2 / 2 / 16	“..., the amount of evidence required for the applicant...”	Wouldn't it be expected this to rather be a <i>combination</i> of amount <i>and</i> quality of evidence?
21	A.2 / 2 / 3 / 16	“...results of research and development, computer modelling and consideration of operating experience, ...”	Results of benchmarking analyses should also be considered, as this may be more prevalent (available) for novel designs and features.
22	B / Figure 1 / page 18		The arrow from the Technology Designer (Vendor) side to the Applicant (Potential Licensee) side may imply that an applicant can't engage in the pre-licensing engagement without a vendor's (<i>optional</i>) VDR being conducted. A clarification note is suggested to be provided regarding this.
23	B / Figure 1 / lower right-hand side box/ page 18	“...Proponent prepares application using REGDOC-1.1.5 and...”	This box seems to imply that REGDOC-1.1.5 is the primary guidance document compared to REGDOC-1.1.1, RD/GD-369, and REGDOC-1.1.3, especially since the latter three documents are not mentioned in this box. However, this may be fine, since in second paragraph of Section 1.1 it is mentioned that REGDOC-1.1.5 be used in conjunction with the aforementioned three documents.
24	B.1 / 1 / last / 19	“The CNSC offers an optional vendor design review (VDR) optional service in this regard.”	Editorial.
25	B.2 / 3 / last / 19	“...for example, for the testing of a thermalhydraulic loop without the use of any nuclear substances.”	In the example provided, it is difficult to understand why an applicant (potential licensee) would bring up to CNSC a proposal for a technology design/project that does not use any nuclear substances. Such facility would not be under the scope of NSCA anyways. It could be subject to CEA 2012 (or future

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			Acts and regulations that may replace CEAA 2012), or other regulations, but not subject to the NSCA.
26	B.2.1 / Activity C / 2 nd sentence / page 20	“If staff recommendations made in the report are approved...”	Editorial suggestion: replace “If” with “When”.
27	B.2.1 / Activity D / 2 nd paragraph – second bullet / page 20	“ May also provide information on...”	The information listed further in this bullet is quite important for an applicant to receive CNSC’s guidance on. Such information should be part of the CNSC’s supplemental guidance letter and not left as a potential (“May also provide...”) information to be provided.
28	B.3.1 / paragraphs 1 & 2 / page 21		Editorial: it seems the two paragraphs contain redundant information with what was already provided a couple of paragraphs before.
29	B.3.1 / 2 nd heading (out of 3) / 4 th bullet / page 22	“The proposed organizational arrangements for the conduct of the activities to be licensed.”	This is already captured in the 1 st heading (last bullet), where it more appropriately seems to belong to.
30	B.3.1 / 2 nd heading (out of 3) / 5 th bullet / page 22	“An estimate of quantity, form, origin and volume of any radioactive waste or hazardous waste that...”	This seems to more appropriately belong under the 3 rd heading (on page 23) that covers radioactive and hazardous waste information.
31	B.3.1 / 3 rd heading (out of 3) / last paragraph /page 23	“For each type of waste that will be produced, the following should be described: ...”	Some of the expected information may not be available at accurate or detail level when the applicant’s proposal is advanced to CNSC for pre-licensing engagement/discussions. A clarification would be needed to acknowledge this, also acknowledging that CNSC’s supplemental guidance letter will be commensurate with the level of information received from the applicant. Otherwise, a clarification should be provided on the level of detail and accuracy expected to be provided in the proposal.