Nalcor Energy – Lower Churchill Project



HUMAN HEALTH RISK ASSESSMENT PLAN

Nalcor Doc. No. LCP-PT-MD-0000-EV-PL-0026-01

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1 PURPOSE

The purpose of the Human Health Risk Assessment Plan (HHRAP) is to outline the key tasks and activities that will occur as part of Nalcor's commitments and requirements in relation to conducting a final baseline pre-inundation HHRA that focuses on human exposures and risks to mercury (Hg) and methylmercury (MeHg) in key country food items.

The HHRAP is intended to serve as a general framework or process document for the key components of the baseline HHRA program, which includes a dietary survey (DS) and a human biomonitoring program (HBP), in addition to the HHRA study itself. Specific details on planning, design, logistics, rationale, implementation, and technical methods and approaches for the baseline DS, HBP and HHRA are provided (or will be provided) within separate and more detailed workplans, as they are developed. In addition, as the DS, HBP and HHRA workplans are developed, there is continued consultation with Health Canada, ENVC, Labrador-Grenfell Health (Population Health Services) and Aboriginal communities, as necessary, to solicit input and feedback and to communicate what will occur within these studies.

At this time, the baseline DS and HBP is complete and a DS and HBP workplan has been prepared under separate cover (LCP-PT-MD-0000-EV-PL-0030-01). The HHRA workplan was developed in 2015 as its design and components will be influenced by the outcomes of the baseline DS and HBP.

In addition, ethics approval for the baseline DS and HBP from the Newfoundland Health Ethics Reseach Authority is attached (see Appendix A). This approval process included the endorsement from ethics or research boards of the NunatuKavut Community Council and the Innu Nation. Furthermore, communication, notification and consultation plans and programs specific to the baseline DS and HBP were implemented. To comply with commitments made in the Lower Churchill Hydroelectric Generation Project (the Project) Environmental Impact Statement (EIS) and conditions of the Environmental Assessment (EA) release, this HHRAP includes consideration of:

- Mitigation objectives performance objectives in respect of each adverse environmental effect;
- Mitigation measures planned to achieve the mitigation objectives;
- Metrics and targets specific, quantifiable, relevant and time constrained;

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 Follow-up or Monitoring Programs – how the Project will include follow-up or monitoring surveys to confirm that mitigation strategies are meeting the mitigation objectives; and

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• Contingency – plan to be implemented should monitoring reveal that mitigation measures have not been successful.

The HHRAP builds on existing information from various existing baseline studies and component studies prepared during the EA process (including the interim HHRA prepared by Golder Associates (2011)), commitments made in the Environmental Impact Statement (EIS) (Nalcor 2009a) and through the Joint Review Panel (Panel) process, and comments provided on the interim 2011 HHRA by Health Canada and ENVC.

Nalcor has committed to completing a final HHRA before the Project changes the conditions of the lower Churchill River (i.e., pre-inundation). NL Reg. 18/12, also referred to as the *Lower Churchill Hydroelectric Generation Project Undertaking Order* releases the Project from environmental assessment and sets conditions for this release that Nalcor must meet. This regulation includes a number of conditions that pertain to Hg, MeHg and human health risks. Further details are provided in Section 7.

Submission of this HHRAP satisfies the condition/requirement in NL Reg. 18/12 that Nalcor prepare and submit to the Minister of Environment and Conservation or the appropriate minister of the Crown, an environmental effects monitoring plan for all phases of the Project, before the commencement of an activity which is associated with, or may affect, the following NL Regulation 18/12 reference matters:

- (iv) methylmercury
- (xii) contaminant levels in country foods
- (xxii) human health

While the HHRA is not environmental effects monitoring (EEM), the HHRA will link closely to EEM programs, and utilize data collected within EEM programs. An HHRA is the most appropriate type of study by which to determine whether or not changes to Hg and MeHg levels within fish and various other country foods may lead to a potential for adverse health effects in human consumers of such food items.

The expected outcome of the HHRAP is a process that will ensure a baseline pre-inundation HHRA is conducted before the Project changes the conditions of the lower Churchill River, and that key supporting studies or other types of studies that will provide critical information to the HHRA effort, are coordinated with the HHRA process so that HHRA data needs are met either before or during the period when the HHRA study is being conducted.

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The HHRAP will allow Nalcor to evaluate and respond appropriately to the findings of relevant follow-up or monitoring programs that relate to Project effects on Hg/MeHg levels in country foods and human exposures and health risks associated with the consumption of country food items that contain Hg and/or MeHg. The HHRAP will also enable Nalcor to identify and inform suitable remedies or mitigation plans should future monitoring data indicate increased Hg/MeHg exposures related to the consumption of key country food items in areas and communities downstream of the Project (e.g., consumption advisories).

2 SCOPE

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The HHRAP addresses potential human health effects of exposure to Hg and MeHg in fish and other key country food items (which could include such food items as: seal, other marine mammals, waterfowl, caribou and other terrestrial game mammals, terrestrial game birds, berries and other harvested plants) for local downstream communities. The EA predicted that consumption advisories would likely apply to fish caught in the main stem of the Churchill River, but not downstream in Goose Bay and Lake Melville. The baseline HHRA will provide a point of pre-inundation and pre-impoundment comparison should there be future increased concentrations of Hg and/or MeHg in key country food items and future increased human exposure rates to Hg and MeHg from the consumption of such country food items.

The HHRAP will be used by Nalcor to guide the HHRA process and provide direction to third party contractors (i.e., those that have been retained or will be retained to conduct the HHRA and the relevant supporting studies and monitoring programs that will provide the key data which the HHRA will evaluate).

Key components of the HHRA effort will include the following:

- Consultation with relevant communities.
- Collection of human hair samples from the relevant communities for baseline determination of Hg and MeHg concentrations.
- Dietary surveys for both country and store-bought foods in relevant communities.
- Conduct a final pre-inundation baseline HHRA that will include new (additional) baseline data, updated exposure information, and that will address key issues and data gaps identified for the interim HHRA, to the extent that is practical.
- Development of a comprehensive monitoring program and health advisory protocol in consultation with Health Canada, Labrador-Grenfell Health (Population Health Services), and the relevant communities, and others, as necessary.

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The key chemicals of concern in all studies conducted to date within the LCP study area (including the EA), and in all regulatory documentation and instruments that pertain to the LCP (such as NL Reg. 18/12), are mercury (Hg) and methylmercury (MeHg). This reflects the well established and well documented fact that Hg and MeHg are routinely the key chemicals of concern when large vegetated areas are flooded for hydroelectric projects. While it is unlikely that other chemicals will need to be evaluated in the baseline HHRA, the HHRA will provide clear rationale and supporting documentation for any and all chemicals that are assessed. As the baseline HHRA relates only to the effects of the LCP, it is reasonable that only chemicals associated with the LCP will be evaluated in the HHRA. At this time, it is believed that the LCPrelated chemicals will be limited to Hg and MeHg. However, the results of baseline sampling and analytical programs for various environmental media and biota (including soil, surface water, drinking water, sediments, fish, seal, and other country food items (as available)) will be reviewed to determine whether or not other chemicals may also merit evaluation in the baseline HHRA. For example, if certain other chemicals are found to be elevated in certain media or biota in the baseline chemistry datasets (above regulatory benchmarks and/or typical reference levels), it is possible that such substances would be considered or evaluated within the baseline HHRA in addition to Hg and MeHg. There may also be literature reviews conducted of other hydroelectric project risk assessments and EAs to determine if such projects in other locations addressed concerns about chemicals other than Hg and MeHg.

While the LCP will involve the use of various chemical products in the construction and operations phases (e.g., fuels, hydraulic fluids, paints, water treatment chemicals such as antifoulants, cleaning products, solvents/degreasers etc.), such chemical uses are carefully managed and many are infrequent and/or contained within LCP buildings and infrastructure. The most likely potential issues associated with the use of chemical products would be accidental spills and releases. If/when these events were to occur, they would be evaluated separately from the baseline HHRA described in this HHRAP, and likely in conjunction with associated spill monitoring and mitigation programs such as the Environmental Protection Plan.

While the baseline HHRA workplan will not be prepared until 2015, the HHRA methods will be consistent with current Health Canada guidance on HHRA (and likely supplemented with HHRA guidance and methods from other relevant jurisdictions as well, such as United States Environmental Protection Agency, World Health Organization, and European Food Safety Authority).

2.1 OBJECTIVES

The overall objectives of the final baseline HHRA are as follows:

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- Focus on human Hg and MeHg exposure from the consumption of important country food items (including fish and seal meat, but potentially including other country food items of concern as well, as noted above). The baseline dietary survey(s) may identify other important country food items beyond fish and seal.
- Consult with relevant communities (including Inuit, Innu and other Aboriginal communities) and address or incorporate the issues and concerns of such communities to the extent that is practical and relevant to the HHRA (this will include but not be limited to issues and concerns raised by members of the Environmental Monitoring and Community Liaison Committee (EM-CLC)).
- Develop partnerships with relevant Aboriginal groups or communities, including Inuit (as represented by the Nunatsiavut Government), Innu and other local Aboriginal communities, and engage/involve such groups in the HHRA process to the extent possible, in order to obtain accurate study area-specific data that can be utilized in the final baseline HHRA.
- Consult with Health Canada and relevant Provincial departments (such as Environment and Conservation), and Labrador-Grenfell Health (Population Health Services), for input into Hg and human health-related issues/concerns, and the design, implementation and communication aspects of human biomonitoring programs, dietary surveys, and country food consumption advisories.
- Address the key issues and data gaps that were associated with the interim HHRA study to the extent that is practical (including the collection of new (additional) baseline data that may be required, and the use of updated exposure information from that used in the interim HHRA).
- Link to and utilize data collected from terrestrial and aquatic environmental effects monitoring programs. Of particular relevance are the fish and seal Hg monitoring programs, but other programs may also provide relevant information for HHRA purposes, such as osprey feather and otter fur Hg concentration data that is being collected under the MeHg EEMP (LCP-PT-MD-0000-EV-PL-0013-01).
- Address all commitments made by Nalcor in relation to Hg, MeHg, country food contamination and human health.
- Link to the design and implementation of baseline human biomonitoring programs (i.e., hair sampling and analyses) and dietary surveys (including both country food items and store-bought food items) in relevant communities, and incorporate the data and outcomes of such programs and surveys into the HHRA.

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- Provide data that can help establish methods and approaches for the design/development, implementation and communication of future consumption advisories for Hg and MeHg, as deemed necessary.
- Utilize existing scientific literature on the current status of human health effects of Hg and MeHg exposure, and regulatory guidance from various relevant jurisdictions that represent current HHRA best practices and approaches.
- Provide regular periodic communication of status and results/outcomes/implications of the HHRA and its supporting data collection activities to the EM-CLC.

3 DEFINITIONS, ABBREVIATIONS AND ACRONYMS

3.1 DEFINITIONS

Environmental Assessment: The evaluation of the Project's potential environmental risks and effects before it is carried out. The EA identifies ways to improve project design and implementation to prevent, minimize, mitigate, or compensate for adverse environmental effects and to enhance positive effects. This includes the EIS (Nalcor 2009), subsequent information requests, and statements issued by Nalcor during the course of the Environmental Assessment hearings in 2011.

Environmental Effects Monitoring: Monitoring of overall Project effects to confirm the predictions of the EIS (Nalcor 2009) and to fulfill commitments.

Human Health Risk Assessment: A study that estimates or determines whether or not people working at, living at, or visiting a given location or area are being exposed, or are likely to be exposed, to concentrations of chemicals in environmental media and/or food items that have the potential to result in adverse human health effects (i.e., toxicity).

4 ABBREVIATIONS AND ACRONYMS

CEAA	Canadian Environmental Assessment Act
EA	Environmental Assessment
EEMP	Environmental Effects Monitoring Plan
EIS	Environmental Impact Statement
EMP	Environmental Management Plan
EPP	Environmental Protection Plan
EMS	Environmental Management System

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ERC	Environment and Regulatory Compliance
ERP	Emergency Response Plan
Gen	Generation
HC	Health Canada
HHRA	Human Health Risk Assessment
HHRAP	Human Health Risk Assessment Plan
HSE	Heath Safety and Environment
Hg	Mercury
JRP	Joint Review Panel
LCP	Lower Churchill Project
MeHg	Methylmercury
ENVC	Newfoundland and Labrador Department of Environment and Conservation

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5 INTERNAL REFERENCES

LCP-PT-ED-0000-EA-SY-0001-01	Environmental Impact Statement and Supporting Documentation for the Lower Churchill Hydroelectric Generation Project
LCP-PT-MD-0000-EV-PL-0011-01	Generation /LTA Environmental Protection Plan
LCP-PT-MD-9112-EV-PL-0001-01	Aquatic Environmental Effects Monitoring Plan
LCP-PT-MD-0000-EV-PL-0013-01	Methylmercury Environmental Effects Monitoring Plan
LCP-PT-MD-0000-EV-PL-0030 -01	Baseline Dietary Survey and Human Biomonitoring (Hair Sampling and Analysis) Program Work Plan

6 PROJECT DESCRIPTION

6.1 MUSKRAT FALLS GENERATION

The Muskrat Falls Generation Facility will include the following sub-components (see Figure 6-1) which are broken down under the five principal areas of the development:

- 22 km of access roads, including upgrading and new construction, and temporary bridges;
- A 1,500 person accommodations complex (for the construction period);
- A north roller compacted concrete overflow dam;
- A south rockfill dam;
- River diversion during construction via the spillway;
- 5 vertical gate spillway;
- Reservoir preparation and reservoir clearing;
- Replacement of fish and terrestrial habitat;
- North spur stabilization works, and
- A close coupled intake and powerhouse, including:
 - 4 intakes with gates and trash racks;
 - 4 turbine/generator units at approximately 206 MW each with associated ancillary electrical/mechanical and protection/control equipment;
 - 5 power transformers (includes 1 spare), located on the draft tube deck of the powerhouse; and

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o 2 overhead cranes each rated at 450 Tonnes

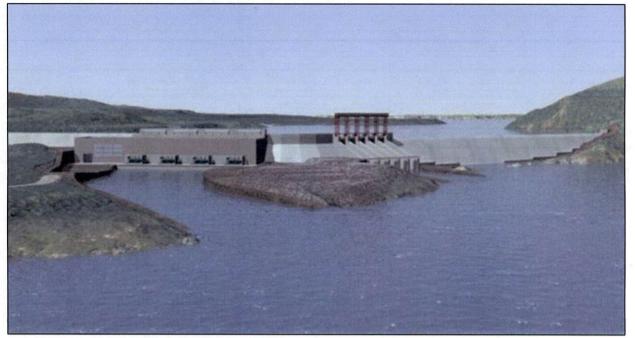


Figure 6-1 Muskrat Falls Generating Facility

6.2 LABRADOR TRANSMISSION ASSETS (LTA)

LTA consists of the ac transmission line system from Churchill Falls to Muskrat Falls (see Figure 6-2), specifically:

- Churchill Falls switchyard extension;
- Muskrat Falls switchyard;
- Transmission lines from Muskrat Falls to Churchill Falls: double-circuit 315 kV ac, 3 phase lines, double bundle conductor, single circuit galvanized lattice steel guyed suspension and rigid angle towers; 247 km long;
- 735 kV transmission line at Churchill Falls interconnecting the existing and the new Churchill Falls switchyards; and
- Labrador Fibre Optic Project (Nalcor's participation in Aliant led initiative).

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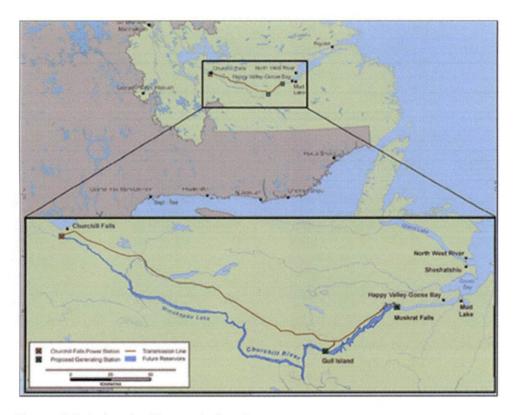


Figure 6-2 Labrador Transmission Asset

7 EXISTING AND PLANNED INFORMATION

Key sources of existing information that relate to the baseline HHRA include, but are not necessarily limited to: the 2011 interim HHRA (and the data used/evaluated within it); monitoring data for Hg and MeHg in environmental media and country food items (including fish, seal) conducted as part of the baseline characterization of the Study Area during the EA process, as well as since EIS submission and/or EA release; Health Canada and ENVC comments on the interim HHRA; any intervenor comments on the interim HHRA; and, any information requests and responses related to the interim HHRA.

The final baseline HHRA will be conducted and designed (to the extent practical) to account for key identified data gaps and comments associated with the interim HHRA, as well as key community, Aboriginal, and other stakeholder issues and concerns that pertain to Hg and MeHg in country food items and potential human health risks from consumption of such food items.

Additional information collection is planned for the final baseline HHRA process. This will include:

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- The collection of data within existing and planned EEMPs on parameters that are relevant for HHRA purposes (the HHRA will source considerable information from, and be linked to current and planned terrestrial and aquatic EEMPs);
- A baseline dietary survey; and
- A baseline human biomonitoring program that will involve the testing of hair samples for Hg and MeHg content among members of relevant downstream communities.

The HHRA process will also utilize existing scientific literature on the current status of human health effects of Hg and MeHg exposure and regulatory guidance from various relevant jurisdictions that represent current HHRA best practices and approaches.

The HHRA process (particularly the dietary survey and biomonitoring program) will also link closely with the Nalcor communications and consultation team programs to obtain relevant information on country food consumption habits, and rates, and to ensure that the collection of baseline hair Hg and MeHg data is conducted in a manner that is sensitive to community concerns and cultural issues, and also occurs in a manner that is transparent and involves trusted community members to the extent possible. Close interaction with the communications/consultation programs will also ensure that key Hg-related health issues that concern the relevant communities are identified and addressed in the HHRA to the extent that is feasible.

Overall, there will be close and frequent interaction between the HHRA process and the teams conducting terrestrial and aquatic EEMPs, and those leading community communications and consultation programs. These efforts are intended to ensure that relevant information needed to conduct a study area-specific baseline HHRA can be collected to the extent possible.

8 **REGULATORY COMPLIANCE**

Nalcor has committed to completing a final baseline HHRA before the Project changes the conditions of the lower Churchill River (i.e., pre-inundation).

8.1 REGULATORY CONTEXT

NL Reg. 18/12, also referred to as the *Lower Churchill Hydroelectric Generation Project Undertaking Order* releases the Project from environmental assessment and sets conditions for this release that Nalcor must meet. Conditions that pertain to Hg, MeHg and human health risks are summarized below (excerpted from NL Reg. 18/12).

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The release of the Project from environmental assessment under section 3 is subject to the following conditions:

- (a) Nalcor Energy shall abide by all commitments made by it in the EIS dated February 2009, and all the EIS Additional Information Requests made by the Project Environmental Assessment Panel and consequently submitted by Nalcor Energy, and the submissions made by Nalcor Energy during the panel hearings and, subsequent to the hearings, to the panel, unless one or more of the commitments, or a part of a commitment is specifically waived by the minister;
- (e) Nalcor Energy shall prepare and abide by the requirements of environmental effects monitoring plans for all phases of the project, and those plans shall be submitted to and approved by, the Minister of Environment and Conservation or the appropriate minister of the Crown before the commencement of an activity which is associated with or may affect one or more of the following NL Reg. 18/12 matters:
 - (iv) methylmercury,
 - (xii) contaminant levels in country foods,
 - (xxii) human health
- (k) Before the commencement of construction, Nalcor Energy shall establish an Environmental Monitoring and Community Liaison Committee to provide feedback to Nalcor Energy and government on the effects of the Lower Churchill Hydroelectric Generation Project.

As NL Reg. 18/12 specifically references commitments made by Nalcor in the EIS, commitments made by Nalcor in response to information requests during the EA Panel process, and commitments made by Nalcor in submissions to the Panel during and subsequent to the Panel hearings, such commitments are, in effect, regulatory requirements.

Nalcor commitments that relate specifically to Hg, MeHg, country food contamination and human health include the following:

- Nalcor will monitor fish Hg concentrations annually for the first ten years following inundation, to verify predictions. Monitoring frequency could then be adjusted, depending on results.
- If the predictions made in the EIS were incorrect, Nalcor has identified consumption advisories as the primary means by which downstream effects from Hg would most likely be addressed, and will work with Aboriginal stakeholders to monitor Hg in fish and

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seals downstream (and potentially other harvested country food items as necessary), and to discuss potential alternatives to consumption advisories.

- Nalcor will conduct an extensive communication program to address consumption advisories.
- For the final baseline HHRA, Nalcor will conduct food consumption surveys and human hair sampling in the communities of Mud Lake, North West River, Happy Valley-Goose Bay, Rigolet, and Sheshatshiu. Additional sampling may be implemented based on Aboriginal collaboration and dietary surveys.
- Nalcor will continue to monitor Hg levels in fish in the reservoirs, and in fish and seal downstream of Muskrat Falls in Goose Bay and Lake Melville, to inform the associated consumption advisories, and will consult government agencies, local communities and Aboriginal groups to effectively communicate advisories specific to each fish species and for seal, as appropriate.
- Nalcor will design extensive monitoring and mitigation programs to ensure that Hg exposure will not produce unacceptable risk to human health. In addition, Nalcor will cooperate with Health Canada in finalizing the baseline HHRA and in designing consumption advisories and communications strategies to ensure that the proposed mitigation strategy is appropriate and effective.
- Proposed mitigation measures and monitoring related to MeHg will include the following:
 - complete a final baseline HHRA to assess the potential human health risk associated with Hg exposure, addressing Health Canada's modelling concerns regarding meal size and frequency of consumption;
 - consult with government agencies, local communities and Aboriginal groups to effectively communicate advisories for specific fish species and for seal, as appropriate;
 - collect additional baseline data on Hg by conducting a food consumption survey and hair sampling in the communities of Mud Lake, North West River, Happy Valley-Goose Bay, Rigolet, and Sheshatshiu;
 - monitor baseline MeHg data in fish and seal in Lake Melville and, depending on the results, consider the possibility of conducting food consumption surveys and hair sampling in other communities, such as Rigolet;
 - monitor MeHg levels after impoundment, in fish in the lower Churchill River, Goose Bay and Lake Melville and in seal downstream of Muskrat Falls to inform consumption advisories; and

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- monitor fish Hg concentrations annually for the first ten years following inundation to verify predictions.
- Nalcor will form a Monitoring and Follow-up Committee comprised of representatives of Aboriginal groups, communities, impartial scientific experts, the Chief Medical Officer of Health and/or the Director of Environmental Health with the Department of Health and Community Services, and federal and provincial regulators. Proposed Committee roles will include:
 - o facilitate communication of monitoring and follow-up objectives;
 - define monitoring and follow-up requirements;
 - consider proposals to meet those requirements;
 - review and advise on results; and
 - o provide feedback to Nalcor.
- Proposed mitigation measures and monitoring related to downstream effects (which were not predicted in the EA) will include the following:
 - work with Aboriginal stakeholders to monitor Hg in fish and seals downstream of Muskrat Falls;
 - collect more baseline data on Hg levels in estuarine fish and seals downstream of Muskrat Falls and in Goose Bay.

Submission of this HHRAP satisfies the condition/requirement in NL Reg. 18/12 that Nalcor Energy prepare and submit to the Minister of Environment and Conservation or the appropriate minister of the Crown, an environmental effects monitoring plan for all phases of the project, before the commencement of an activity which is associated with or may affect the following NL Reg. 18/12 referenced matters:

- (iv) methylmercury
- (xii) contaminant levels in country foods
- (xxii) human health

While HHRA is not environmental effects monitoring (EEM), the HHRA will link closely to EEM programs, and utilize data collected within EEM programs.

The LCP is also subject to Sections 32(2) and 35(2)(b) of the new Fisheries Act. The following sections of the Fisheries Act Authorization (13-01-005) are applicable to the HHRA:

 Section 6 – The Proponent shall undertake an EEM Program as outlined in the LCP Aquatic Effects Monitoring Program – Muskrat Falls dated February 2013, to monitor and verify the predicted effects of the proposed development from a fish and fish

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habitat perspective including downstream effects, methylmercury bioaccumulation in fish and fish entrainment at the Muskrat Falls facility by:

 6.3: Methyl mercury bioaccumulation shall be monitored annually to determine levels in resident fish species, including seals, both within the reservoir and downstream as per established monitoring schedule, to record and report peak levels and subsequent decline in background levels.

Details related to the Aquatic EEMP can be found in the LCP Aquatic EEMP (see LCP-PT-MD-9112-EV-PL-0001-01).

9 ENVIRONMENTAL EFFECTS MANAGEMENT

Should adverse human health effects be predicted in relation to the consumption of fish and other country food items (in either baseline or operations phases), such effects would be managed primarily through consumption advisories. The HHRAP includes tasks and activities related to research and review of existing science and policy that underlies the issuance of consumption advisories. Thus, if/when such actions are necessary, Nalcor will be well positioned to apply the most sound and defensible science and policy in deciding whether or not to issue advisories, determining what the advisories will entail, and communicating the advisories to affected communities and stakeholders. In the event of consumption advisories, the HHRAP will link closely with the community communication and consultation programs. In addition, the HHRAP will ensure that there is consultation with Health Canada, Labrador-Grenfell Health (Population Health Services), ENVC, the EM-CLC, Aboriginal groups (including the Innu Nation, and Inuit as represented by the Nunatsiavut Government) and, prior to the issuance of consumption advisories.

10 ENVIRONMENTAL EFFECTS MONITORING

As noted, HHRA is not environmental effects monitoring (EEM); however, the HHRA will link closely to EEMPs, and utilize data collected within EEMPs. The final baseline HHRA will involve or link to existing and planned EEMPs, which will consist of:

 Follow-up Programs – studies or surveys designed and implemented to evaluate the predictions of the EA and to determine the effectiveness of any measure taken to mitigate the adverse environmental effects of the Project; and

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 Monitoring Programs – studies or surveys designed and implemented to determine whether or not the Project is implemented as proposed, and that mitigation measures proposed to minimize the Project's environmental (or human health) effects are implemented and effective.

10.1 PROGRAMS AND PROTOCOLS

The Project has committed to conduct follow-up and monitoring programs to evaluate the effectiveness of the effects management plans, and to determine if expansion or reduction or deletion of the indicated programs is appropriate (with justification). This would apply to the following, as appropriate:

- data collection during construction;
- data collection during operations; and
- follow-up and monitoring reporting.

Programs/protocols for data collection relevant to the final baseline HHRA are briefly discussed in the following subsections. In general, data collection programs for the LCP include metrics that are specific, quantifiable, relevant and time constrained. The goal is to collect meaningful data in a focused, defendable, repeatable approach, within an appropriate timeline to ensure that mitigation (if deemed necessary) is appropriate. Where it is determined that mitigation is not appropriate or can be improved, a contingency plan would be presented that the LCP would incorporate in accordance with their adaptive management approach.

10.1.1 Baseline Data Collection

Baseline data relevant to Hg/MeHg in various environmental media, biota and country food items has been collected and continues to be collected in terrestrial and aquatic EEMPs until inundation occurs, to provide an adequate baseline data set by which post-inundation changes can be compared, tracked and interpreted in terms of potential for human exposure and health risk. Baseline data collection will continue until inundation occurs and has recently been expanded upon to allow collection of data on additional parameters relevant to MeHg formation and accumulation rates, and human country food consumption patterns, that were not previously available.

Two key surveys/programs that will occur pre-inundation, and that will provide key information to the final baseline HHRA process are a dietary survey and a human biomonitoring program (involving sampling and testing of hair for Hg and MeHg).

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10.1.1.1 Dietary Survey

Dietary surveys conducted in relevant communities will seek to obtain data on such issues and items as what country foods are harvested and consumed, whether the harvesting occurs in areas that may be affected by the Project, the frequency of consumption, whether or not there are seasonal or cultural constraints on consumption (e.g., is a food item preserved or stored and consumed year-round or is it consumed only when harvested fresh and in season?), the portions (including tissues and organs) of country food items that are consumed, and how the food items are typically prepared/cooked prior to consumption.

Dietary surveys may need to occur in multiple years (post-inundation) to address participation rates, and diet variability over time.

Local dietary information will be key in determining the need for and details of Hg/MeHg fish consumption advisories (and any advisories that may eventually be needed for other country food items).

Information obtained during the dietary surveys may also lead to exploring research questions regarding the influence of different food preparation/cooking methods on the levels of Hg and MeHg in edible portions of country foods, and how these different methods may affect human Hg and MeHg exposure associated with country food consumption.

10.1.1.2 Human Biomonitoring Program

Collection of human biomonitoring data (i.e., hair sampling and analysis for Hg and MeHg) in relevant communities will provide a baseline for total human exposure to Hg and MeHg. This will enable future biomonitoring programs (during operations) to detect a change (increase or decrease) in human Hg and MeHg exposure. Biomonitoring data will also provide actual measures of Hg and MeHg exposure within relevant communities and provide a useful line of evidence for the HHRA beyond modelled hazard quotients.

10.2 DATA COLLECTION DURING OPERATIONS / FOLLOW-UP PROGRAMS

HHRA-relevant data that are collected during the baseline programs (i.e., diet survey, human biomonitoring program, terrestrial and aquatic EEMPs) will continue to be collected following inundation and during the Project operations phase.

Some modifications to the monitoring programs (for future operations phase programs) may occur based on the final baseline HHRA outcomes and could include additions or deletions of parameters, addition or deletion of stations, changes to media or food items that are sampled, and changes to timing and frequency of sampling events. Details regarding the frequency,

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timing, and locations of future sampling or survey events will be decided following the completion of the baseline DS, HBP and HHRA, as well as the continued data collection from aquatic and terrestrial EEMPs. These studies will provide key data and outcomes that will inform and guide any future programs that may need to occur.

The LCP will consult with Health Canada, Labrador-Grenfell Health (Population Health Services) and other agencies and groups as the details and design of specific future monitoring programs are determined.

As it is expected that increased Hg and MeHg levels in environmental media and key country food items would not manifest for a number of years post-inundation, there is no anticipated need to conduct dietary surveys and biomonitoring programs on an annual basis. Rather, it is expected that outcomes of the ongoing EEMPs, which will be tracking Hg and MeHg concentration trends in media and food items, will inform on the need for and timing of future operations period dietary surveys and/or biomonitoring programs (e.g., if MeHg trends up in commonly consumed fish over a few monitoring/sampling events, that may serve as a trigger for follow-up studies to confirm consumption patterns and/or determine if changes have occurred to baseline human tissue levels of Hg/MeHg). In the event that a future DS and HBP is warranted, it would be anticipated that the same communities (as surveyed and sampled in the baseline DS and HBP) would likely be targeted. However, follow up studies with human subjects are often not able to target the same individuals, for a number of reasons (out-migration, death, illness, refusal or lack of interest to participate etc.). It should also be recognized that it could be a number of years between baseline DS and HBP studies.

Depending on the outcomes of operations phase EEMPs, dietary surveys and biomonitoring programs, the need for other types of follow-up studies may be identified.

The need for mitigation or other remedies to address elevated Hg/MeHg levels in country food items and subsequently elevated potential human health risks (such as consumption advisories), will also be determined based on the outcomes of operations phase EEMPs, dietary surveys and biomonitoring programs.

At this time, contingency plans are not anticipated in relation to Hg/MeHg levels in key country food items, and potentially in human tissues (as determined through biomonitoring programs). Any necessary changes to the anticipated LCP procedures or mitigation plans would be addressed through the adaptive management approach, if and as appropriate.

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11 WORK PLAN / CORE TASKS AND ACTIVITIES

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This section identifies the core tasks and activities that relate to the key components of the HHRA (as noted in Section 2, above), and briefly outlines the approaches by which these tasks/activities will be implemented or addressed, and the HHRA objectives (Section 2) achieved.

For the final pre-inundation baseline HHRA and its supporting data collection efforts, Nalcor will conduct the following tasks and activities:

- 1) Ensure that responses to JRP recommendations by the federal and provincial governments, which pertain to human health, MeHg, and country foods contamination, are accounted for in the HHRA process and supporting data collection activities.
- Ensure that expectations, issues, claims and concerns of key stakeholders, including the relevant Aboriginal groups, that relate to human health, MeHg, and country foods contamination are accounted for in the HHRA process and supporting data collection activities.
- 3) Ensure that the design of the HHRA builds upon or incorporates the relevant findings and recommendations of the interim HHRA, and addresses any key data gaps or issues associated with the interim HHRA (including comments on the interim HHRA by the Province, including Labrador-Grenfell Health (Population Health Services), and Health Canada).
- Conduct baseline dietary surveys for country foods and store-bought foods in relevant communities.
- 5) Conduct baseline human biomonitoring programs for Hg and MeHg (consisting of human hair sampling and analyses) in relevant communities.
- 6) Ensure that the HHRA and its supporting data collection activities are conducted according to current standard best practices and HHRA guidance.
- 7) Identify key technical resources or guidance that relate to establishing and implementing consumption advisories for Hg and MeHg, to enable a sound understanding of the underlying science and policy decisions that may lead to issuance of consumption advisories.
- 8) Identify the key information needs or inputs that will be required for a technically sound and comprehensive HHRA (as well as any key supporting or supplemental studies) and the ability to respond to regulatory and stakeholder issues/concerns. This includes such activities as dietary studies and human biomonitoring programs, but may also include refinements or additions to current terrestrial and aquatic monitoring programs.

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9) Identify potential collaborations that may facilitate key data collection efforts and key studies that would support the HHRA and its supporting data collection activities.

Nalcor has retained independent third party expertise to advise and guide the HHRA-related tasks and activities and provide technical review services and/or advice in relation to collected data, procurement, study designs/approaches, study outcomes/results, and the implications of HHRA outcomes with respect to monitoring programs design and refinement, and the need to consider consumption advisories.

11.1 ANTICIPATED SCHEDULE (TENTATIVE)

- The baseline dietary survey and human biomonitoring program was completed in December, 2014 and February, 2015.
- The bulk of the HHRA is anticipated to occur over the fall of 2015 and winter of 2016. However, some elements of the HHRA may be initiated prior to this (e.g., using outcomes of dietary survey to develop consumption rates and exposure scenarios, interpretation of hair Hg and MeHg data, and possibly selected literature reviews in support of HHRA tasks and activities).

12 RECORDS / REPORTING

It is anticipated that outcomes of EEMPs, the dietary surveys, and biomonitoring programs will be reported separately. The final baseline HHRA report will utilize the data from EEMPs, the dietary survey and biomonitoring program but will be separate from these other studies. Relevant summaries of EEMP data, dietary survey and biomonitoring program outcomes are expected to be included in the final baseline HHRA report as technical appendices.

The final baseline HHRA report, including any appropriate data summaries and technical appendices, will be prepared and submitted to ENVC, Labrador-Grenfell Health (Population Health Services) and Health Canada following its completion. The HHRA report will also be made available to Aboriginal groups and the general public.

13 REFERENCES

JRP. 2011. Lower Churchill Hydroelectric Generation, Joint Review Panel Report, August 2011.

Nalcor (Nalcor Energy). 2009a. Lower Churchill Hydroelectric Generation Project Environmental Impact Statement.

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APPENDIX A: HEALTH RESEARCH ETHICS BOARD APPROVAL

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Ethics Office Suite 200, Eastern Trust Building 95 Bonaventure Avenue St. John's, NL A1B 2X5

November 3, 2014

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Ms Theresa Repaso-Subang Golder Assoicates Ltd 6925 Century Avenue, Suite #100 Mississauga, Ontario L5N 7K2

Dear Ms Repaso-Subang:

Reference #14.132

RE: Nalcor Energy Lower Churchill Hydroelectric Project Baseline Dietary Survey and Human Bio monitoring Program

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Board. *Full board approval* of this research study is granted for one year effective July 24, 2014.

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Revised consent forms, dated July 2014, approved
- Approval letter from NunatuKavut government, acknowledged
- Approval letter from Innu Nation, acknowledged
- Respondent Information form, approved
- Frequency of Harvested Food consumption survey, approved
- Frequency of Market Food consumption survey, approved
- Advertisement, approved

MARK THE DATE

This approval will lapse on July 24, 2015. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date; you may not receive a reminder, therefore the ultimate responsibility is with you as the Principle Investigator. The information provided in this form must be current to the time of submission and submitted to HREB not less than 30 nor more than 45 days of the anniversary of your approval date. The Ethics Renewal form can be downloaded from the HREB website <u>http://www.hrea.ca</u>.

email: info@hrea.ca

Phone: 777-6974

FAX: 777-8776

Ms Repaso-Subang Reference #14.132 November 3, 2014

The Health Research Ethics Board advises THAT IF YOU DO NOT return the completed Ethics Renewal form prior to date of renewal:

- Your ethics approval will lapse
- You will be required to stop research activity immediately
- You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again

Lapse in ethics approval may result in interruption or termination of funding

It is your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate. You are also solely responsible for providing a copy of this letter, along with your application form, to the Office of Research Services should your research depend on funding administered through that office.

Modifications of the protocol/consent are not permitted without prior approval from the Health Research Ethics Board. Implementing changes in the protocol/consent without HREB approval may result in the approval of your research study being revoked, necessitating cessation of all related research activity. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREB website) and submitted to the HREB for review.

This research ethics board (the HREB) has reviewed and approved the research protocol and documentation as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; ICH Guidance E6: Good Clinical Practice* and applicable laws and regulations. The membership of this research ethics board is constituted in compliance with the membership requirements for research ethics boards as defined by *Health Canada Food and Drug Regulations Division 5; Part C.*

Notwithstanding the approval of the HREB, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you every success with your study.

Sincerely,

Dr Ferr) Brunger, PhD (Chair Non-Clinical Trials) Ms. Patricia Grainger, (Vice-Chair Non-Clinical Trials) Health Research Ethics Board

email: info@hrea.ca

Phone: 777-6974

FAX: 777-8776