REQUEST FOR PROPOSALS (RFP)

Provincial Radiopharmacy and Nuclear Medicine Consumable Acquisition

(MSNS 130018)

ADDITION #7

October 16, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. **STATEMENT**: As per Addendum #5, attached are the minutes from the second Mandatory Proponent’s Meeting which occurred on October 15, 2013.

- End of Addendum #7-
PROVINCIAL RADIOPHARMACY RFP
October 15, 2013, Proponents Meeting – 9:00 a.m. – 10:30 a.m. Followed by a Site Tour

ATTENDANCE: Kim Weagle, Richard Wilson, Christina Kelly, Brian Martell, Alain Cote (Cardinal Health)

TELECONFERENCE: Telephone connection started at 9:00 a.m.; at 10:15 we were joined by Christine Henault and Jeanette Benoit (Lantheus)

1. Introductions and Welcome

2. Brief Overview – Kim

Kim repeated her opening comments as per the September 26, 2013 meeting, the Minutes of which have been posted as an Addendum on the government website.

3. Document Review

May require more than one contract. Distribution agreement was mentioned – heading for a Provincial Radiopharmacy, GMP. Want to have Cape Breton and Yarmouth under the same contract and have the same pricing for generators and kits, same shipping costs.

PART A

Kim reviewed the changes and revisions made in the Addendums posted to date on the website.

Page 9: Closing Date – remains as October 18, 2013 at 2:30 p.m. Atlantic time.

Page 10: Section 8 – stressed using the website for up-to-date information.

Page 11: Mr. Cote asked if it was possible to write notes on the documents – Kim advised that he was to request in writing a “word formatted” RFP as per addendum #1 and he could make notes on any page. He advised that he would put this request in immediately and comply with the closing date and time.

Page 12: Section 13 – Clinical Acceptability – Brian stressed that we need enough time to evaluate the different products at all sites across the province. An Addendum to this affect was added to the website.

Page 14: Section 20 - 5 year contract - this was discussed at length at the September meeting with a response posted at Addendum #3.
Page 17, Section 22: Not required to initial each page. #7 was also addressed – DINs required – it was revised to include “if applicable”. These questions were addressed in Addendum #3.

Page 18: It was stressed that this page MUST be signed and completed. It is the General Terms and Conditions Section 22 which starts on page 17.

Page 19, Section 23: Proposal Submission Form - Must be completed.

Page 20 Appendix A1: It was stressed that these are estimates only. Addendum #2 and Addendum #3 stressed the deletion of some items and the addition of a new chart.

Page 21: Shipping - We would like two estimates – one for shipping everything to Halifax and one for shipping to other sites as requested, for example – cold kits.

Page 24 - 9th Box: – Addendum #2 addresses previous question on this – this was pointed out.

Page 25: As previously noted, Cape Breton’s start date – remove January date and insert “TBA”.

Page 26 Appendix C1 Compliancy Checklist: To be completed by adding a check mark to confirm compliancy and the page number for the appropriate sections for review ease of reference. Also, a preferred method would be for a proponent to added “agreed” within each section of the RFP document confirming compliancy.

Page 28 Appendix D1 Standard Form Contract: – Standard from our legal department.

Page 38 Appendix F1: Full Disclosure of Financial Contributions: – Complete and sign off; if there is nothing to disclose please place an “N/A” or “0”.

PART B

The only sections that were discussed were the differences between PART A and PART B requirements.

Page 43, Section 37: - Requested layout, tabs are different. Tab3 and Tab 4 are required for Partnership; Tab 1 and Tab 2 are required for Supplied Goods. If submitting proposals for both models, all 4 Tabs should be used.

Page 44, Section 42: References – Canadian preferred.

Page 44, Section 43.1.1: – At the September meeting a discussion took place on the 80% figure – all vendors agreed this was not possible; they all stated they would need distributions agreements in place by their legal departments: This question was addressed in Addendum #3.

Page 57: 6th box – shipping to DHAs daily – wording is: are you “willing to provide”; not mandatory.

Page 58: 1st box – define costs in proposal; 4th box – GMP.

Page 59: Estimate of $150,000 – Kim read the question in the 5th box which asks what are you willing to put toward this project.
Page 59: 2nd box - Maintenance Service contracts – Proponent’s responsibility identify up front.

Page 60: 1st box - We provide the staff and space.

Page 61 – 63 - Construction plans and GMP report were included in RFP.

Page 61: – change proposed date for Cape Breton to “TBA”

Addendum #6 was posted on Friday, October 11, 2013.

4. **Adjournment**

   The meeting adjourned at 10:30 a.m. These Minutes will be posted as Addendum #7.

5. **Site Tour**

   Respectfully Submitted,
   Krista MacDougall, Recording Secretary
REQUEST FOR PROPOSALS (RFP)

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ADDENDUM #6
October 11, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. **STATEMENT:** Proponents providing proposals to the Supplied Goods Solution and Partnership Solution are to provide a response to the following:

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe your generator shielding and give the approximate transport index for your 6 Curie and 7.5 Curie generators.</td>
</tr>
</tbody>
</table>

2. **STATEMENT:** Proponents providing proposals to the Partnership Solution are to provide responses to the following:

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide confirmation to commit to ongoing compliance to GMP standards over the duration of the contract.</td>
</tr>
<tr>
<td>Confirm your ability to operate under CNSC regulations over the duration of contract.</td>
</tr>
<tr>
<td>Confirm your ability to secure a drug establishment license and/or any other licensing required to operate the Provincial Radiopharmacy.</td>
</tr>
</tbody>
</table>

End of Addendum # 6-
REQUEST FOR PROPOSALS (RFP)

Provincial Radiopharmacy and Nuclear Medicine Consumable Acquisition

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A D D E N D U M #5
October 9, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. QUESTION: A prospective RFP Proponent requested if it would still be possible to provide a proposal on this RFP if, due to the timing of when they became aware of this RFP process, they failed to attend the mandatory Proponents’ Meeting?

   ANSWER: The Mandatory Proponents’ Meeting is an essential component to ensure all Proponents are familiar with the onsite conditions to provide a proposal on the Partnership Model of this RFP and ensure Proponents have a clear understanding of the requirements of this RFP. Due to the importance of this project to the Province and the provisions set out in the RFP package, it has been decided to hold a second on site Proponent’s Meeting, which is mandatory for any Proponent who did not attend the first Proponent’s Meeting to attend in person. This meeting is scheduled for 15 October 2013, from 0900hrs to 1200hrs, room 3309, at the Halifax Infirmary Site. It is not mandatory for those proponents who attended the first Proponent’s meeting to attend, however, it is open to all Proponents to attend either in person or via teleconference call (Dial In Phone # 1-888-653-2299; Passcode:2786974). A tour of the department will follow the meeting. Minutes of this meeting will be posted by way of addendum on the government website; www.gov.ns.ca/tenders.
2. **QUESTION:** We have some further inquiries as to the wording in the RFP document and hope to have the opportunity to revise sections contained within Appendix D1 & D2 Standard Form Contract. Is this possible?

**ANSWER:** Thank you for your questions provided on October 3, 2013. We respect that these questions are important to your considerations however we are in not in a position to answer them at this point in time in that they take the form of negotiations in relation to the final contractual language as between preferred proponent(s) and MSNS. Such negotiations will occur only as anticipated under sections 19 and 46 of the RFP.

3. **QUESTION:** With regards to I131 quantities, was there going to be a # of capsules or vials provided as opposed to # of patients per period for the therapy capsules and/or solution? As mentioned it is difficult to determine the pricing structure per volume even if in the brackets we discussed during our meeting. We need, for example, something like this:

- 5 capsules at 370 mBq each (or 10 mCi) / month
- 10 vials at 370 mBq each (or 10 mCi)/month

It would be greatly appreciated and would likely facilitate your own evaluation of offers if this information was provided.

**ANSWER:** Capital Health is the only CRP site that will be treating patients for hyperthyroidism or thyroid cancer. We treat 1 to 3 patients a week for hyperthyroidism and 1 to 2 patients a week for thyroid cancer. We cannot predict what dose the physician will request for treatment, only the range.

CDHA presently receives a standing order of 50 mCi a week of oral solution. This will probably continue and this 50 mCi is almost always enough to do all the thyroid uptakes, whole body surveys and the treatments for hyperthyroidism at CDHA.

The ablation treatments are ordered separately, on an as needed basis. We do not know how much until the patient is evaluated and the decision made by the referring physician. The majority of patients requires 100 mCi and in almost all cases it will be solution and 1 to three patients are treated weekly for thyroid cancer, routinely 2.

Two other sites use capsules for thyroid uptakes and order 5 capsules at a time. The numbers are low, less than 8 patients a month (total for both sites) on average.
When the CRP opens it is possible that we will supply those sites with oral solution or based on pricing it may be feasible to move to capsules for CDHA as well.

- End of Addendum # 5-
REQUEST FOR PROPOSALS (RFP)

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ADDENDUM #4
October 2, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. **STATEMENT:** Attached is the meeting minutes from the September 26, 2013 Mandatory Proponent’s Meeting.

2. **QUESTION:** Would it be possible to obtain word version of the RFP document with all the changes from the Addendums?

   **ANSWER:** No, original documentation will remain the same as we typically do not revise the original RFP. Addenda will cover all changes.

3. **QUESTION:** Why is the district not using shielding containing depleted uranium?

   **ANSWER:** The following is the response from our Radiation Safety Officer:

   **Consideration of Depleted Uranium for Shielding in Mo99/Tc99m Generators**

   **Introduction**
   Supply of Mo99/Tc99m generators of high activity can contain depleted uranium as a means of shielding. It offers much more radiation protection than lead and tungsten. One company quotes its use in generators of 6Ci (222 GBq) or higher.

   **Background**
   CDHA will have to get depleted uranium listed on the licence. The exact wording is to be determined, however, in consultation with departments in New Brunswick, that already
have this in place, it would be part of generator shielding with the maximum per device as unlimited.

CNSC has advised it would be listed as "DU, Used as an integral part of the Mo99/Tc99m generators"

Places locally that use depleted uranium in shielding include:

- **Cardinal Health** (826 distribution and 847 processing licences), Vaughan, ON: RSO Willie Regits 614-757-4120
- **Tyco Healthcare Group** (824 distribution), Pointe Claire, QC: RSO H. El Guerouaoui 514-695-1220 (3336)
- **Regional Health Authority B**, (862), Saint John, NB: RSO Julie Boyle 506-648-6852
- **Horizon Health**, Moncton, NB (862): RSO Paul Colosimo 506-857-5283
- **Regional Health Authority A** (862), Moncton, NB: RSO Christine Noel 506-862-4127
- **Regional Health Authority A** (862), Bathurst, NB: RSO Daniel Thibeault 506-544-2445

Gary Wilson spoke with one site that ships their generators back to the manufacturer. They prepare TDG documentation and export or other documentation as the shipment returns to the USA. They do not have any issues with the shipment once it was established. It takes approximately 45 minutes to prepare the return shipments (2-3 generators at a time). They do not have to break down the generators so save on that time.

**Process**

- Apply for an amendment to the processing licence to include depleted uranium as an integral part of the shielding.
- Ensure the return of the generator to the manufacturer is in place.
- Obtain training on paperwork required for shipment over international borders that is in addition to routine transport of dangerous goods paperwork.

**Summary**

It is possible to add depleted uranium to our licence as long as it is clear that we would be able to return it to the manufacturer and not have to be responsible for any disposal ourselves.

4. **QUESTION:** I have a question that would require as speedy a reply as possible, and I am certain the other vendors would also agree:

Christina provided a list of patient and exams per site – as discussed, this is not as useful as one might think. The most useful tool would be to state which product and how much is used per site so that we can assess more accurately the required volumes. This
would not change the pricing levels as we understand you are seeking equal pricing for all. Please advise if the above information could possibly be made available.

**ANSWER:** The present situation may change somewhat after implementation of the CRP and on a go forward basis, as we look for ways to maximize efficiencies.

Page 54 of the RFP lists the min and max volumes of cold kits we require as a group for the provincial radiopharmacy. The products will be purchased and distributed appropriately to each site.

Comparison can be made relating the min max volumes to the Nuclear Medicine studies list April 1, 2010 to March 31, 2013. This will give an idea of how many kits each site is presently using over the span of the year. As stated above, this may vary once the provincial radiopharmacy is operational.

5. **QUESTION:** Can you please clarify question 19 in regards to the daily Tc-99 needs. There seems to be a conflict with the daily requirements and with the generator sizes requested in the RFP. For Tuesday for example the requested Sunday 7.5 curie generator would leave the site with approximately 3.62 curie Tuesday morning but the stated amount needed in Addendum #3 question 19 for Tuesday is (160Gbq) which = 4.32 curie. Which means the requested generator size is leaving the site short and not meeting the Tuesday needs.

**ANSWER:** Theoretically a 7.5 curie generator will yield approximately 3.62 curie at 0700 and the yield from the expiring generators will supply the rest.

The provincial radiopharmacy will adjust productions for CDHA with second and possibly third productions to meet the need. The 40 GBq for CDHA is the present situation and will be adjusted as required when the provincial radiopharmacy is operational.

**First Column, CDHA:**
CDHA is presently using approximately 40 to 45 GBq in the am to prepare products. That is the number listed in the first column. The 40 GBq is a part of the daily required activity for CDHA. The afternoon products are prepared from second production.

6. **QUESTION:** Secondly, can you verify is the IWK & DHA section including Yarmouth & Cape Breton. If they are included can we have the estimated daily activity that only the radiopharmacy will need for CDHA and the districts being supplied by the radiopharmacy (therefore excluding Cape Breton & Yarmouth needs). Keeping in mind of course we will not be committing MSNS to this amount but only to provide the most optimized generator solution for their needs.
ANSWER: Second Column, IWK & other DHAs:
The second column is a list of the requirements for all DHAs and IWK except Yarmouth and Cape Breton. This list is the minimum daily requirements with a small buffer added. All these sites except IWK will receive one daily shipment. IWK will routinely receive one daily shipment but due to proximity to the provincial radiopharmacy will have a little more flexibility.

7. QUESTION: In Addendum #3 the iodide chart is provided however I need further clarification. The various sizes needed are useful; however what is the quantity used of each dose? And I would need to know what is therapeutic and what is diagnostic.

ANSWER: See yearly usage for quantities and divide by 12 for monthly usage or 52 for weekly usage. Routinely the schedule is much the same week to week.

At CDHA I131 solution is used for all I131 whole body surveys, thyroid uptakes, treatments for hyperthyroidism and almost all of the ablation treatments. CDHA receives a standing order for 1.850 GBq (50 mCi weekly). This is used to prepare uptake and whole body survey doses and treatments.

Other sites use capsules for I131 thyroid uptakes and I131 whole body surveys. Please see table. Over the one year period of stats provided CDHA was the only site to treat patients for hyperthyroidism or thyroid cancer.

There were 70 thyroid ablations, most of whom received 3.7GBq (100mCi). Some received 1.1 GBq (30 mCi), 5.5 GBq (150 mCi) or 7.4 Gbq (200 mCi) as ordered by referring physician.

**I131 sodium iodide capsules and solution**

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<td>5550</td>
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Nuclear Medicine Studies April 1, 2010 to March 31, 2011

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NT...not tracked

- End of Addendum # 4-
PROVINCIAL RADIOPHARMACY RFP
September 26, 2013, Proponents Meeting – 10:00 a.m. – 2:00 p.m.

Attendance: Kim Weagle, Tena Fleet, Christina Kelly, Brian Martell, Andrew Ross, Susan Delaney, Evelyne Orel (DraxImage), Tara Doyle (Mallincrodt), Len Ducker and Bill O’Driscoll (GE), Mireille Daidge and Marie Vianney (Lantheus), Mike McNeil (CHS)

1. Introductions and Welcome

2. Brief Overview – Kim

The document will be reviewed, mandatory criteria in each section will be highlighted. Guidelines will also be discussed, any questions are to be asked during the topic at hand. Any deferred questions will have their responses posted as an Addendum on the government website.

3. Document Review

The document was reviewed, discussions took place, comments and suggestions made:

Page 5: Section 1.2 – may require more than one contract; may need a “phase in approach” once current contracts are finished.

Page 7: Basis of selection – both Len and Evelyn asked if possible to do partial supplies, have a third party involved. Len brought up the question of a distribution agreement – partnership agreement and separate agreement for supplies – need to provide answer: This question will be addressed in Addendum 3.

PART A

Page 9 – Outlined schedules, Section 6. Tentative start date was asked, January 1st was the response.

RFP closing date of October 10th deadline – question was if this could be extended: This question will be addressed in Addendum 3.

Page 9-10: Section 7 – The proposal process was stressed, no faxes or emails. Time line is set, nothing will be accepted after the 1430 Atlantic Time Closing Time. Nine CDs, no USB sticks. One printed copy – everything must be signed where indicated.
Page 10: Section 8 – stressed using the website for up-to-date information. All questions and answers will be posted within 72 hours of receipt. **Today’s questions will be addressed in Addendum 3.**

Page 12: Section 13 – Clinical Acceptability – we need enough time to evaluate the different products. Need to standardize for the Province – do a thorough evaluation. Len asked if a month was necessary, Andrew answered that it would depend on the product and the procedure, and if the product was used every day. Len suggested a mutual agreement between all parties. Other company representatives felt the same: **This question will be addressed in Addendum 3.**

Page 14, Section 19: If a successful agreement with party “A” cannot be reached then we will proceed to party “B”. Clarify liability – final terms and negotiations – compliance vs preferred terms, preferred terms are negotiable.

Page 14, Section 20: Period of Contract - discussion took place on this topic with respect to the term of years and firm pricing: **This question will be addressed in Addendum 3.**

Page 15, Section 20.3 – Phased In Approach - This was briefly discussed, will be worked on at a later date with the successful company. We will honor existing contracts as per their terms and conditions contained within each contract.

Page 17, Section 22 – It was stated that the responses do not require initials on each page. #7 was questioned – some vendors do not have DINs – it was requested that this be revised and include “if applicable”: **This question will be addressed in Addendum 3.**

Page 19: It was stressed that this page MUST be signed and completed.

Page 20 Appendix A1: it was stressed that these are estimates only. Addendum #2 on the website answers some previous questions. This was discussed at length, vendors cannot give lump prices, can give ranges. It was decided that Christina would provide 10 products of I31 capsules and solutions and receive unit prices so all of the vendors’ prices could be compared and provide the number of curies of Technetium 99m required at each site every day: **This question will be addressed in Addendum 3.**

Page 20 – Items Listed in Chart – it was requested that 3 items be removed from the chart and from the patient data sheet as they are not approved: I123 Radiochem, I131 MIBG tx, and Y90: **This question will be addressed in Addendum 3.**

Page 21, #2, #5 & #6 – This was discussed at length; there is a cost sharing formula for blended shipping costs, to include Cape Breton and Yarmouth – have one contract, everybody pays the same costs. Blended fee is to ship generator – vendor can break down what it would cost to ship generator and/or to ship supplies to other locations. One generator is going to the school for training, in January, February and March each year. Len brought up the issue of a distribution agreement being drawn up and signed – set out accountability, be able to do audits, adverse event reporting – other companies agreed: **This question will be addressed in Addendum 3.**

Page 23 7th Box – Disposal of depleted radium – sent back to the US. Recommendations from safety officer were taken into consideration – our license would need to be changed. Requires more information from safety officer: **Still waiting for feedback from various parties. A response will be posted separately once it has been finalized.**

Page 24 -5th Box – this requires a response – elution start time in Halifax is listed in the RFP and includes delivery times to other sites. We are looking for a guaranteed delivery time.
Page 24 9\textsuperscript{th} Box – Addendum 2 addresses previous question on this.

Page 25 Cape Breton start date – remove January date and insert “TBA”.

Page 26 Appendix C1 Please add the word “agreed” to the appropriate sections, fill out and complete chart for review ease of reference.

Page 28 Appendix D1 – Standard form from our legal department. Any legal questions can be forwarded to Kim who will forward to our legal department.

Page 34 – does not require an immediate signature

Page 38 – complete and sign off; if there is nothing to disclose please place an “N/A” or “0”.

PART B

Evelyn asked if it was possible to carry on with their regular customers – response was yes, but not to discuss this RFP process.

Page 41 - 43 – requested layout

Page 44, Section 43.1.1 – discussion took place on the 80% figure – all vendors agreed this was not possible; they all stated they would need agreements in place by their legal departments: This question will be addressed in Addendum 3.

Page 61 – change proposed date for Cape Breton to “TBA”.

Page 73, Basis of Payment – referenced Schedule A1, page 35 – vendor invoice.

Len brought up a discussion on the cost of getting products to Halifax and distribution. We are open to different solutions – Kim read the last box on page 57 which contains the proposed schedule.

If there are any questions with respect to the site plans for the engineers, please forward these questions to Kim and she will direct them to the correct person.

4. Adjournment

The meeting adjourned at 2:30 p.m.

Respectfully Submitted,
Krista MacDougall, Recording Secretary
REQUEST FOR PROPOSALS (RFP)

Provincial Radiopharmacy and Nuclear Medicine Consumable Acquisition

(MSNS 130018)

ADDENDUM #3
September 26, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

PRE BIDDER'S MEETINGS – RFP PROVINCIAL RADIOPHARMACY/NUCLEAR MED SUPPLY

PARTICIPANTS:
-Brian Martell, Kim Weagle, Dr. Andrew Ross, Christina Kelly, Tena Fleet, Mike MacNeil, Susan Delaney, Evelyne Orel, Tara Doyle, Len Ducker, Bill O'Driscoll, Maria Vianney, Mireille Daigle

Minutes of the Meeting will be posted at a later date.

The following Questions and responses were received/given which will form part of this RFP:

1. **QUESTION**: How do you deal with 3rd party vendor in a partnership option?

   **ANSWER**: Indicate your company’s range of nuclear medicine products and your ability to supply other products through a 3rd party vendor. If your company is willing to entertain this, please outline potential impacts required. (ie: distribution agreement, additional administration fees, etc.)

2. **QUESTION**: What if the partnership model cannot service a specific DHA?

   **ANSWER**: The partnership would have to supply and encompass the needs for any specific DHA either by supplying products directly or via the 3rd party option as outlined in answer #1.

3. **QUESTION**: Who would vendors invoice and who owns the contract?
Proponents are to refer to schedule A1 & A2 Basis of Payment for further details. If there is a 3rd party arrangement with the successful proponent, then the 3rd party would invoice the proponent. If there is no 3rd party arrangement in place and we have a direct contract with the vendor, the vendor would invoice us directly.

4. **QUESTION:** Concerns that the October 10th, 2013 deadline date is too tight? We request an extension?

**ANSWER:** The closing date of October 3, 2013 for questions will remain the same as stated in Part A & B of the RFP. However, an extension to the closing date for RFP submission has been granted. Section 7.1 and 34.1 has been revised to the following:

Sealed proposals shall be signed, executed, and dated and shall be directed to:

Kimberley Weagle  
Merged Services Nova Scotia, Strategic Sourcing  
C/o Fishermen’s Memorial Hospital  
P.O. B ox 1180  
14 High Street  
Lunenburg, Nova Scotia B0J 2C0

No later than 1430 Hours Local Atlantic Time on October 18, 2013 (the “Closing Time”)  
In case of dispute as to time requirements stipulated in this RFP, the hospital system clocks at the Fishermen’s Memorial Hospital shall be taken as accurate.

All other sub-section within section 7 & 34 will remain valid and unchanged.

5. **QUESTION:** What is the tentative date to implement the new contract?

**ANSWER:** Proponents are to refer to Appendix B1 & B2 of the RFP for proposed implementation dates for each DHA.

6. **QUESTION:** Does a DHA require one month trial of product for the Clinical Acceptability sections of Part A & B of the RFP?

**ANSWER:** Mutual agreement will occur with the evaluation sites and proponent(s) in order to determine the volume of trial product required for an acceptable clinical trial. However, it is important to note that all DHAs have an opportunity to trial various products and clinical acceptability is not solely being decided or evaluated by one DHA.

7. **QUESTION:** Are evaluation products to be provided at n/c?

**ANSWER:** Yes, see the Clinical Acceptability sections of Part A & B of the RFP.

8. **QUESTION:** Is it 5 years firm pricing? Are the 2 option years allowing escalators?
9. **QUESTION:** During negotiations do proponents need to have clarity and terms and conditions nailed down prior to entering into negotiations?

**ANSWER:** If proponent’s term and conditions conflict with the RFP’s Mandatory Criteria, we encourage vendor use the question section to seek clarification. Note: Not all terms and conditions within the RFP are mandatory and those can be discussed during negotiations if your company does not agree with them.

10. **QUESTION:** If a proponent has a contract which will expire in 2015, will the contract be honored?

**ANSWER:** We will honor any existing contracts in place and will use any existing opt out clauses. If the proponent(s) is successfully awarded a new contract, we will be expecting proponent(s) to work with the DHA’s to blend their existing and new contracts.

11. **QUESTION:** Is there an initial signoff required on each page?

**ANSWER:** Proponents do not have to initial each page of their response.

12. **QUESTION:** As per sections 22 & 49 of this RFP; Term #7 – these products do not have DIN #’s. Can you indicate “if applicable”?

**ANSWER:** The following term has been revised to:

7. All proposed product (if any) shall comply with and all applicable laws, codes and standards including the Canadian Nuclear Safety Commission. If applicable, the Proponent shall provide DIN(s). The Proponent shall ensure the Transport Canada regulations in relation to the Transportation of Dangerous Goods materials are followed.

13. **QUESTION:** As per statement contained on Pg. 21 # 2 – What if there is a more efficient way to address shipping? Will you consider other options?

**ANSWER:** Yes, we are open to consider options. However, we are concerned that rural DHAs would incur significant increased shipping costs. A blended shipping cost is required for the province so everyone pays the same price.

14. **QUESTION:** Why are DHA 3 and other DHAs’ generator shipments not indicated?

**ANSWER:** Their requirements are being prepared and distributed from the provincial pharmacy in Halifax. The generators will be milked in CDHA and sent to the other DHAs as required.

15. **QUESTION:** Please explain the quantity of the Gen 11 GBq qty of 11 located in Appendix A1 & A2?

**ANSWER:** Please refer to Addendum 2 for the response.
16. **QUESTION:** Proponents would require CDHA to sign a distribution agreement for the shipping of products to DHAs that reflects accountability such as adverse events, audits, etc. How will these be addressed?

**ANSWER:** Distribution agreements may be negotiated with successful proponent(s) depending upon solution that is provided within this RFP.

17. **QUESTION:** Are the quantities indicative of patient #'s or procedures?

**ANSWER:** It reflects an estimate of # procedures.

18. **QUESTION:** Can proponents insert a table indicating the activity with varying price ranges for iodine 131 oral and I131 capsules?

**ANSWER:** Please see the following table to assist in pricing of the I131 capsules and oral solution:

<table>
<thead>
<tr>
<th>Capsules</th>
<th>Solution</th>
</tr>
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<tbody>
<tr>
<td>MBq</td>
<td>mCi</td>
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<tr>
<td>0.555</td>
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<td>74</td>
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<td>5550</td>
<td>150</td>
</tr>
<tr>
<td>7400</td>
<td>200</td>
</tr>
</tbody>
</table>

19. **QUESTION:** How many mCi’s are required daily for the generators in order to determine a efficient solution to the requirements of the generators? Will the DHAs consider different solutions if they are proven to be efficient?

**ANSWER:** Please see the following yields in order to assist to providing delivery solutions. The DHAs are receptive to exploring efficiencies related to other generators and deliveries that may not be outlined with the RFP.

Approximate daily technetium -99 levels required to service all DHAs and IWK based on current workloads:
Calibrated for 0700 Monday to Friday

<table>
<thead>
<tr>
<th>Day of Week</th>
<th>Activity GBq</th>
<th>Activity GBq</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDHA *</td>
<td>IWK &amp; other DHAs</td>
<td></td>
</tr>
<tr>
<td>Monday</td>
<td>45</td>
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<tr>
<td>Friday</td>
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<td>100</td>
</tr>
</tbody>
</table>

*CDHA would require second elution and third as needed.

Also, CDHA has flexibility to use more of second or third elutions to meet the needs of other sites, as the generators would be housed at CDHA.

20. **QUESTION:** I131 MIBG tx, I123 radiochem and Y90 have not received Health Canada approval. We request the removal of these products from Appendix A1, A2 and example list of year exams provided within Addendum 2.

**ANSWER:** These products are to be deleted from all RFP documents and any required response from proponents.

21. **QUESTION:** Why is the district not using shielding containing depleted uranium?

**ANSWER:** We are in the process of obtaining further clarification from the CDHA Radiation Safety Officer and will advise shortly.

22. **QUESTION:** What does “indicate your company’s solution to late product delivery when/if the DHA incurs a penalty from other affected parties” mean?

**ANSWER:** We are looking for guaranteed delivery times/solutions and how Proponents manage their delivery schedule.

23. **QUESTION:** What does “state the features that are unique and/or exclusive of this product” mean?

**ANSWER:** This question has been addressed in Addendum # 2.

24. **QUESTION:** When viewing the addendum on the government website, it appears addenda #2 and addenda #1 are contained within the same file. Is this correct?

**ANSWER:** Responses to Addendum have to be loaded as one master document; not separately. The lastest posted will be first in the master document and followed in descending order.
25. QUESTION: Can you please clarify exactly what you are looking for in the following question: Impact on teaching and training/research services with regards to radiopharmaceutical production and sciences?

ANSWER: We are an academic institution with responsibilities to teach both technologists as well as medical doctors in nuclear medicine the details of radiopharmacy. Thus, would like to know what impact or potential opportunities would exist with regards to the academic aspects related to the proposal submitted. How teaching might be involved, affected etc. possible positive impact in terms of research opportunities.

26. QUESTION: If a vendor is only bidding on the supply model and not the partnership model does the vendor need to remain for the rest of the meeting?

ANSWER: No.

27. QUESTION: Is the tour of the facility mandatory?

ANSWER: No, it is mainly for those considering solutions for the partnership model. However, all are welcome on the tour.

28. QUESTION: May Proponents speak with departments they serve in regards to existing contracts when issues arise and not discuss the RFP. Can they still conduct regular business with sites?

ANSWER: Yes, they can continue regular customer support as long as they do not discuss any related details with the RFP.

29. QUESTION: What does 80% of products covered in Section 43 on page 44 of the Basis of Selection for partnership mean?

ANSWER: Section 43.1.1 has been replaced with the following:

In order for a Proponent’s Proposal to be considered for this model, a Proponent shall supply most of Gen Product lines required.

30. QUESTION: Who will be responsible for the Distribution of the product from the central pharmacy within the Partnership model?

ANSWER: Please refer to page 57 of Appendix B, last block. We looking for possible partnership on shipping; however, this is not a mandatory criteria and depending on the cost and efficiencies for distributing the product as required by the successful proponent if a partnership model is award, the DHA may exercise their right to go directly to the market on this type of service. However, any assistance or expertise that can be provided would be welcomed.

- End of Addendum # 3-
REQUEST FOR PROPOSALS (RFP)

Provincial Radiopharmacy and Nuclear Medicine Consumable Acquisition

(MSNS 130018)

ADDENDUM #2
September 23, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. **QUESTION:** For scheduling purposes can you please advise how long the mandatory site visit is.

   **ANSWER:** Site visit meeting commences at 10 am with a site tour to follow. Length of time is undetermined as it will depend on the review of the RFP and any questions/discussions to be had with Attendees.

2. **QUESTION:** In section 24 Appendix A1 in the first row a) 11 GBq does not make sense as no generators come in that size from any vendor. b) It is also not clear how many they receive monthly. We need to know how many units monthly. If it could be broken down by week that would be easier. c) Is this only for the three months of the year on top of their regular orders?

   **ANSWER:** a) Sunday cal, 111GBq (3 C generator); b) 3 generators over 3 month period...1 per month; this year the dates are January 28, February 11, and March 13, 2014. c) Yes, this is on top of our regular orders.
3. **QUESTION:** For the gallium, thallium, I131 and I131 MIBG what is the actual dosage. Some of these range from 1mCi to 150mCi. We need to know what measurement to quote on.

**ANSWER:** Please quote cost per mCi, MBq or GBq and if it differs depending on how much is ordered please supply price list with range of activity. Gallium 67 doses are 0.3 GBq (8mCi); 201 Thallium 0.111 GBq (3 mCi); I 131sodium iodide capsules for thyroid uptakes 0.555 mBq (15 uCi), I131 sodium iodide capsules for therapies range from 0.185 GBq to 7.4 GBq (5 mCi to 200 mCi...same as above, please supply price list with range of activity.

4. **QUESTION:** a) For the I131 are you looking for diagnostic caps or therapeutic? b) By oral I131 do you mean solution?

**ANSWER:** a) looking for I131 sodium iodide capsules for thyroid uptakes and therapies...please quote for both; b) I131 oral should read I131 liquid (solution).

5. **QUESTION:** For Octreoscan I need to know the number of doses ordered because the measurement GBq is not helpful as each institution doses patients differently and Octreoscan is ordered as a unit not by specific dose.

**ANSWER:** approximately 40 doses per year

6. **QUESTION:** In Section 24 a Tuesday calibrated generator is requested. Unfortunately Mallinckrodt does not manufacture on Tuesdays. Only on Sunday, Monday, Wednesday & Friday. a) Is the site willing to choose from a Monday or Wednesday calibrated generator instead and if so will the size stay the same? b) Also, is DH9 open to sharing how many MBq/Ci they use on a daily basis. By knowing the exact amount needed on a daily basis Mallinckrodt has helped tailor solutions for customers in the past that proves to be most efficient and saves cost.

**ANSWER:** a) Companies are free to quote generator costs based on whatever calibration day meets the requirements on the RFP cost effectively; b) Attached is an example list of the yearly exams per DHA; however, we are not bound by these volumes as outlined in Appendix A1 & A2 of the RFP.
7. **QUESTION:** In section 5 Appendix B1, the 11th question states: “*State the features that are unique and/or exclusive of this product.*” Can you please clarify which product it is you are referring to?

**ANSWER:** Generators...wet/dry, special features, efficiencies, shielding...etc.

8. **QUESTION:** Appendix A1 – Supplied Goods Model Pricing Proposal – there are no monthly quantities indicated for the radioactive products (3rd table, 1st page), only max and min GBq sizes shown. Will there be an updated table with approximate quantities provided? Very difficult to propose pricing with no volume.

**ANSWER:** Attached is an example list of the yearly exams per DHA; however, we are not bound by these volumes as outlined in Appendix A1 & A2 of the RFP.

9. **STATEMENT:** The following clause will replace sections 12.5 and 39.4 of the RFP:

   A Site Examination/tour of the Provincial Radiopharmacy site will occur during the last part of the Proponents’ Meeting.

- End of Addendum # 2-
## Nuclear Medicine Studies April 1, 2010 to March 31, 2011

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REQUEST FOR PROPOSALS (RFP)

Provincial Radiopharmacy and Nuclear Medicine Consumable Acquisition

(MSNS 130018)

ADDITION #1

September 20, 2013

The RFP Documents, including Addenda, shall be amended and new clauses and specifications added and become part of the Contract Documents as follows:

1. **QUESTION:** I just wanted to address the section regarding Cape Breton’s transition to the NS radiopharmaceutical contract. In section 25 page 25 it states Cape Breton will transition January 1st 2014. However, we have a contract with Cape Breton until December 31st 2014. Was this a typo, or do they intend to break a contract?

   **ANSWER:** This was a typo. It should state TBD. However, depending on award(s) with successful proponents, their previous contracts may become part of the negotiations as the DHA would want to move over to the new contracts, collectively. There is no intention to break a contract.

2. **QUESTION:** We would like to receive the MS-Word version of the RFP in order to input our responses to the questions.

   **ANSWER:** Word Format documentation can be provided. However, please note that these documents are being provided for you to input your responses only and no changes to our language will be permitted. All information that is provided in the original RFQ pdf file and original pdf addenda will be the legal documents that are considered binding for this process. In order to obtain a Word formatted version, proponents must email kweagle@ssdha.nshealth.ca with their request.
3. **QUESTION:** I am in receipt of the abovementioned RFP and have started reviewing the documents. Would you be so kind as to confirm where and if we are to indicate that we will be submitting a proposal, and that we will be attending the meeting next week.

**ANSWER:** Proponents are not required to register if they will be submitting a proposal or attending the upcoming meeting. Upon arrival at the Mandatory Proponent’s meeting, a sign in log will be required to be completed to confirm attendance of the meeting.

4. We have received and reviewed the RFP and have a few questions in preparation for your mandatory meeting by the proponents on September 26, 2013 at 10am. We understand the importance of attending in person and wish to participate. Therefore, given that the meeting is fast approaching we would like to know if participating via videoconference/ teleconference would be an option.

**ANSWER:** Proponents must attend in person.

5. Secondly, there are two distinct parts to the RFP and we would like to know which part will be discussed during this meeting.

**ANSWER:** Both will be discussed.

6. Is the mandatory site visit necessary if a vendor is only bidding on part A as a supplier and not the radiopharmacy partnership?

**ANSWER:** Proponents must attend in person to meet the Mandatory criteria part of the RFP regardless of which part a proponent is responding to.

- End of Addendum # 1-