GHSI EMERGENCY RADIONUCLIDE BIOASSAY LABORATORY NETWORK: SUMMARY OF A RECENT EXERCISE

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The Global Health Security Initiative (GHSI) established a laboratory network within the GHSI community to develop their collective surge capacity for radionuclide bioassay in response to a radiological or nuclear emergency. A recent exercise was conducted to test the participating laboratories for their capabilities in screening and in vitro assay of biological samples, performing internal dose assessment and providing advice on medical intervention, if necessary, using a urine sample spiked with a single radionuclide, 241Am. The laboratories were required to submit their reports according to the exercise schedule and using pre-formatted templates. Generally, the participating laboratories were found to be capable with respect to rapidly screening samples for radionuclide contamination, measuring the radionuclide in the samples, assessing the intake and radiation dose, and providing advice on medical intervention. However, gaps in bioassay measurement and dose assessment have been identified. The network may take steps to ensure that procedures and practices within this network be harmonised and a follow-up exercise be organised on a larger scale, with potential participation of laboratories from the networks coordinated by the International Atomic Energy Agency and the World Health Organization.

INTRODUCTION

The Global Health Security Initiative (GHSI) is an informal network of countries formed in 2001 to ensure health-sector exchange and coordination of practices in confronting risks to global health posed by chemical, biological and radio-nuclear threats, as well as by pandemic influenza (1). The member countries/organisations of the GHSI are Canada, France, Germany, Italy, Japan, Mexico, the UK, the USA and the European Commission. The World Health Organization (WHO) is a technical advisor. As part of the GHSI partnership, an annual meeting of Health Ministers is held to foster dialogue on topical policy issues and promote collaboration. Other initiatives involving senior health officials as well as policy, technical and scientific personnel take place on a regular basis, focussed on risk management, communications, chemical events, radio-nuclear threats, pandemic influenza and global laboratory cooperation.

The GHSI Rad-Nuc Threats Working Group (RNWG) was created to facilitate sharing and collaboration on policies and capability development to enhance public health preparedness and response to radiological and nuclear threats. As a result of discussions and consultations, the RNWG decided to establish a laboratory network to improve the collective surge capacity for radionuclide bioassay within the GHSI community. Within this network, laboratories can share their expertise through training activities, exercise their preparedness through intercomparisons, develop new capabilities through collaborative R&D and assist in bioassay analysis when multiple laboratories are required following an emergency.

In 2013, the network laboratories were surveyed on their current capabilities in emergency radionuclide bioassay and the technological and operational gaps they had identified in this area. Based on the survey results, an intercomparison exercise was organised in late 2014 to test the participating laboratories for their response capabilities in screening and in vitro assay of biological samples, performing internal dose assessment and providing advice on medical intervention.
when necessary. Eight laboratories from seven countries (Canada, France, Germany, Italy, Japan, UK and USA) participated. In addition to testing, the exercise also provided an opportunity for countries to share and compare their policies and practices for assessing internal contamination, and for the network to identify common technological or operational priorities for future collaborative work.

METHODS AND MATERIALS

Exercise design

The exercise was designed to be an intercomparison of emergency capabilities for screening, bioassay, dose assessment and medical advice. While it was somewhat realistic, the scenario was deliberately designed to be manageable by most of the participating laboratories in terms of the required sensitivity for the measurement as well as resource demands (i.e. laboratories were not asked to work overtime).

Based on the consensus of the RNWG, it was decided to exercise the participating laboratories with a urine sample spiked with a single radionuclide that has been identified to be high risk (2-4). The following scenario and parameters were chosen or considered:

- **Acute intake of** $^{241}$Am (1.50 MBq) via ingestion by a man with physical characteristics similar to a 'Reference Man' described by the International Commission on Radiological Protection (ICRP)(5).
- **Urine collection** started 24 h after the suspected intake and lasted for 24 h. One 100 ml urine sample from this collection would be sent to each laboratory (to mimic a spot sample).
- **The laboratories** were required to report their results at short, predetermined intervals in order to simulate an emergency response.
- **The level of contamination** in the scenario was chosen to accommodate the bioassay capabilities previously demonstrated by some of the participating laboratories (6), as well as to approach the dose thresholds for medical intervention recommended by national or international authorities (4, 7).

Sample preparation and distribution

Based on the above design, a calculation using IMBA Plus® (version 4.0.36, provided by ACJ & Associates, Inc., 129 Patton Street, Richland, WA, USA) determined that the spiking level for $^{241}$Am in urine should be $4.3 \text{ Bq \, l}^{-1}$. Blank urine was collected from one healthy unexposed individual, preserved and spiked with $^{241}$Am (RM S2/22/10, Amersham, Buckinghamshire, UK) following the standard procedure of the National Calibration and Reference Center for Bioassay and In Vivo Monitoring, Health Canada, which is certified to the International Organization for Standardization (ISO) 9001:2008 standard (8). The spiked urine sample was then divided into 100 ml aliquots; one was sent to each participating laboratory by a commercial carrier.

Scheduled reports

Tables 1 and 2 summarise the messages sent to the participating laboratories and the questions to be addressed in the scheduled reports. ‘Message No. 1’ was sent out soon after the urine samples were picked up by the commercial carrier along with questions for the laboratories to address when submitting the ‘6-Hour Report’ and the ‘72-Hour Report’. This message was sent by email to each laboratory individually with a designated confidential lab code provided. Considering the time required for sample delivery and potential delay over the weekend, the laboratories were advised to start the exercise at a convenient time; they were not required to start the exercise at a specific time or immediately after receiving the samples. The ‘6-Hour Report’ and the ‘72-Hour Report’ were required to be submitted no later than 6 and 72 h, respectively, once the exercise started.

‘Message No. 2’ was sent by email to each laboratory soon after its ‘72-Hour Report’ was received along with questions for the laboratories to address when submitting the ‘96-Hour Report’. This message provided essential information for the assessment of intake and radiation dose. The ‘96-Hour Report’ was due in 24 h after receiving ‘Message No. 2’.

RESULTS AND DISCUSSIONS

Response to reporting schedule

Overall, the participating laboratories submitted most of the required reports as scheduled, although the starting time varied from lab to lab due to the difference in the time required for sample delivery and

<table>
<thead>
<tr>
<th>Table 1. Messages sent to the participating laboratories.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Message No. 1 ‘A urine sample has been shipped to your lab for screening and bioassay of a radionuclide in it. Once you receive the sample, you may start working at a time convenient to you.’ (Sent soon after samples were picked up by the commercial carrier.)</td>
</tr>
<tr>
<td>Message No. 2 ‘The urine sample (100 ml) you received is from a man (70–80 kg, 170–180 cm) of mid-twenties who was suspected to have had a single intake of the radionuclide through food consumption. Urine collection from this person started 24 h after the suspected intake and lasted for 24 h. The sample you received is a fraction of this 24-hour urine collection.’ (Sent immediately after receiving the ‘72-Hour Report’.)</td>
</tr>
</tbody>
</table>
customs clearance, time zone issues and/or a schedule conflict with other work commitments. All laboratories submitted the required ‘6-Hour Report’ on time, indicating that the laboratories are capable of screening samples in a short time period. Three laboratories delayed the submission of the ‘72-Hour Report’ due to either the bioassay method(s) requiring more time or the bioassay work was paused over the weekend. One laboratory slightly delayed the submission of its ‘96-Hour Report’ due to issues related to weekend communication. Lab 003 exited the exercise after submitting its ‘72-Hour Report’.

Results for ‘6-Hour Report’

All the participating laboratories reported that the sample was ‘radioactive’ and provided a brief description for the techniques used for sample screening (Table 3). Four screening methods/techniques were used by the laboratories, with gamma spectrometry and liquid scintillation counting being the most widely employed. Within a short counting period (2–3 h), gamma spectrometry would show a small but visible peak at 60 keV, which indicates the possible presence of $^{241}$Am in the sample. Liquid scintillation counting using a small fraction of the sample, with or without alpha/beta discrimination, would indicate above-background radioactivity in the sample and the presence of alpha emitter(s). Gross alpha/beta analysis is a very popular technique for sample screening; however, in this exercise, only Lab 007 used it. Interestingly, inductively coupled plasma mass spectrometry (ICP-MS) was also used for screening (Lab 002 and Lab 005). ICP-MS measurement does not tell if a detected mass is for a radionuclide, but it does indicate the potential presence of the radionuclide

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Screening techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>Gamma spectrometry (HPGe) showed a small peak of 60 keV; Liquid scintillation counting for gross alpha showed a result slightly above the background; ICP-MS screening showed the possible presence of $^{241}$Am.</td>
</tr>
<tr>
<td>003</td>
<td>Gamma emitter(s) indicated using a whole-body counter; No alpha emitters indicated because of small volume of sample.</td>
</tr>
<tr>
<td>004</td>
<td>Gamma spectrometry indicated the suspected presence of $^{241}$Am; Liquid scintillation counting for gross alpha/beta confirmed the presence of alpha emitter(s).</td>
</tr>
<tr>
<td>005</td>
<td>Gamma spectrometry (HPGe) found several small peaks around 59, 63 and 92 keV with poor counting statistics; ICP-MS analysis found a significant amount of an element with a mass of 88.</td>
</tr>
<tr>
<td>006</td>
<td>Gamma spectrometry indicated the presence of $^{241}$Am; Liquid scintillation counting for gross alpha/beta measurement with 1 ml sample showed results less than the detection limit.</td>
</tr>
<tr>
<td>007</td>
<td>Gamma spectrometry indicated the presence of $^{241}$Am; Gross alpha/beta analysis (using 20 ml of the sample) gave results of $4.2 \pm 0.4$ and $28.5 \pm 3.4$ Bq $\text{l}^{-1}$ for alpha and beta, respectively. The beta spectrum suggests the presence of $^{90}$Sr/$^{90}$Y.</td>
</tr>
<tr>
<td>008</td>
<td>Gamma spectrometry on the sample (3-h counting) showed a peak at 59.5 keV, characteristic of $^{241}$Am; Liquid scintillation counting for gross alpha/beta measurement with 5 ml sample (2-h counting) indicated the presence of alpha emitter(s) but not beta emitter(s).</td>
</tr>
<tr>
<td>009</td>
<td>Gamma spectrometry; Liquid scintillation with alpha/beta discrimination.</td>
</tr>
</tbody>
</table>

| Table 2. Questions for participating laboratories to address when submitting their reports. |
|---------------------------------|-----------------|-----------------|
| 6-Hour Report                   | 72-Hour Report  | 96-Hour Report  |
| When did you start?             | Which radionuclide is in the sample? | What is the intake activity? (Bq) |
| Is the sample radioactive?      | What is the activity of this radionuclide in the sample? and the uncertainty associated with the activity at 95 % CI? | What is the projected 50y CED to the person from this intake? (mSv) |
| How did you know? (<100 words) | How was the analysis conducted (method and procedure, method for estimating uncertainty)? (<200 words) | Which methods/tools did you use when conducting intake and dose assessment? (<100 words) |
|                                 |                 | Would you recommend any medical intervention to this person? |
|                                 |                 | What intervention? |
|                                 |                 | Which guideline did you follow when you make the recommendation? (<200 words) |
with such a mass. Lab 003 used a whole-body counter to screen the sample, as the above-mentioned four techniques were not available.

Results for ‘72-Hour Report’

For the bioassay measurement, diverse methods/techniques for sample treatment, separation, measurement, QA/QC and estimation of uncertainties were used by the participating laboratories (Table 4). Alpha spectrometry was used by four laboratories (Lab 004, Lab 005, Lab 006, Lab 007) for the measurement of $^{241}$Am in the urine samples following separation using chromatographic methods (solid-phase extraction or anion exchange) and electro-deposition. Lab 002 also separated $^{241}$Am from the sample using a chromatographic method but measured it by ICP-MS. Lab 008 and Lab 009 quantified $^{241}$Am in the sample using gross alpha liquid scintillation counting and gamma spectrometry, with a counting time of 17 and 68 h, respectively. The advantages and disadvantages of different methods/techniques for emergency bioassay have been discussed previously; however, it is worthwhile to note that bioassay methods that deliver results in hours rather than days are always desired for emergency population monitoring and management as early medical interventions, if indicated necessary by bioassay results, help reduce radiation-induced health risks more effectively.

Table 5 summarises the bioassay results reported by the participating laboratories with uncertainties at the 95% confidence interval (CI). As mentioned above, the spiked testing level for $^{241}$Am is 4.3 Bq l$^{-1}$. The calculated bias from the reported results in Table 5 falls between $-12$ and $+19\%$, which is well within the acceptable range of $-25$ to $+50\%$ recommended by ISO 28218, an international standard developed for occupational bioassay. Currently, there is no international standard for emergency bioassay available. Lab 005 and Lab 007 reported the measurement results for other radionuclides, although only $^{241}$Am was spiked in the sample. These results indicate potential contamination from impurities in the tracers and chemicals used by the laboratories, or more possibly interferences to the measurements from background radiation depending on the techniques employed. Post-exercise discussion revealed that the reported $^{241}$Pu signal by Lab 007 was actually caused by the presence of $^{40}$K in the urine sample.

Table 4. Methods/techniques used for bioassay in the participating laboratories.

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Bioassay methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>Solid-phase extraction separation using DGA column (Eichrom®); Measurement using HR-ICP-MS (Thermo Element XR); QA/QC: tracer application ($^{241}$Am), creatinine correction, method validation using NIST traceable QC materials.</td>
</tr>
<tr>
<td>003</td>
<td>Failed. Activity is too low to be measured by using a whole-body counter.</td>
</tr>
<tr>
<td>004</td>
<td>Sample mineralisation using nitric acid and H$_2$O$_2$; Anion exchange column separation (Dowex 1 × 8 CI form) and solid-phase extraction (DGA); Electro-deposition of Am and Pu on stainless steel discs; Measurement using alpha spectrometry; QA/QC: tracer application ($^{243}$Am and $^{242}$Pu).</td>
</tr>
<tr>
<td>005</td>
<td>Sample mineralisation using nitric acid; Anion exchange column separation (Dowex 1 × 8 CI form); Electro-deposition of Am on a counting disc; Measurement using alpha spectrometry; QA/QC: tracer application ($^{243}$Am, $^{235}$U, $^{242}$Pu).</td>
</tr>
<tr>
<td>006</td>
<td>Sample mineralisation using nitric acid and H$_2$O$_2$; Solid-phase extraction separation using TRU column (Eichrom®); Electro-deposition of Am on a counting disc; Measurement using alpha spectrometry; QA/QC: tracer application ($^{244}$Am).</td>
</tr>
<tr>
<td>007</td>
<td>Measurement of $^{241}$Am and $^{239}$Pu using alpha spectrometry following ion exchange separation and electro-deposition; Measurement of $^{90}$Sr using liquid scintillation counting following phosphate isolation and extraction chromatography; Measurement of $^{241}$Pu (suspected) using gross beta liquid scintillation counting.</td>
</tr>
<tr>
<td>008</td>
<td>Measurement of a sub-sample (5 ml) using gross alpha liquid scintillation counting (17 h); QA/QC: a urine sample from a healthy donor was counted similarly for blank correction.</td>
</tr>
<tr>
<td>009</td>
<td>Measurement using gamma spectrometry (HPGe, 68-h counting); GUM for uncertainty estimation.</td>
</tr>
</tbody>
</table>
Results for ‘96-Hour Report’

Table 6 summarises the assumptions, methods and tools used by each laboratory when performing the intake and dose assessment. All the laboratories inferred from ‘Message No. 2’ that the ICRP ‘Reference Man’ model (5) could be used for intake and dose assessment, while some of the laboratories also recognised the limitation of using it. ICRP biokinetic and dosimetric models were used by all the laboratories, in the form of national or international guidelines or as computerised tools (IMBA, AIDE, MONDAL, DCAL). Some of the laboratories used multiple tools to verify the assessment, which is a very good practice.

Table 7 presents the reported intake and the 50 y committed effective dose (CED) from each laboratory. As mentioned above, the exercise was designed starting with an acute intake of 1.50 MBq $^{241}\text{Am}$ through food ingestion. The calculated 50y CED for a ‘Reference Man’ is 306 mSv. Table 7 shows that for all but one laboratory, the reported intake of $^{241}\text{Am}$ and the resulting CED are very close to 1.5 MBq and 306 mSv, respectively, with a bias no more than $\pm 20\%$. Although the bioassay result reported by Lab 005 (Table 5) is very close to the testing level, the reported intake and dose values are substantially different from the expected values. Post-exercise discussion revealed that this was due to a mistake regarding the date on which the urine sample was collected. The results for intake and the CED obtained from re-calculation (not shown in this article) are quite comparable with those submitted by the other laboratories. Lab 005 and Lab 007 also reported the calculated intake and dose for radionuclides other than $^{241}\text{Am}$. As discussed above, these are the results of tracer impurities, contamination or background interference.

Table 8 presents the medical advice provided by the participating laboratories. All recommended treatment (immediate or not) with diethylene triamine penta acetate (DTPA) (with or without specified dosage) in reference to a dose threshold recommended by one or more national or international guidance documents. The role of qualified physicians and other factors were also identified by some of the laboratories as important considerations when a decision on treatment needs to be made. Some of the laboratories mentioned the need for further monitoring to evaluate the treatment efficacy. Note that some guidance documents recommend the use of a dose threshold of

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**Table 5. Bioassay results reported by the participating laboratories.**

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Bioassay results at 95% CI (Bq l$^{-1}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>$^{241}\text{Am}$: 3.8 ± 0.41</td>
</tr>
<tr>
<td>003</td>
<td></td>
</tr>
<tr>
<td>004</td>
<td>$^{241}\text{Am}$: 4.12 ± 0.44</td>
</tr>
<tr>
<td>005</td>
<td>$^{241}\text{Am}$: 4.1 ± 0.45; $^{242}\text{Cm}$: 0.13 ± 0.04</td>
</tr>
<tr>
<td>006</td>
<td>$^{241}\text{Am}$: 4.4 ± 0.7</td>
</tr>
<tr>
<td>007</td>
<td>$^{241}\text{Am}$: 4.1 ± 0.5; $^{239}\text{Pu}$: 0.1 ± 0.05; $^{90}\text{Sr}$: 2.2 ± 0.4; $^{241}\text{Pu}$: 26 ± 5</td>
</tr>
<tr>
<td>008</td>
<td>$^{241}\text{Am}$: 4.2 ± 0.2</td>
</tr>
<tr>
<td>009</td>
<td>$^{241}\text{Am}$: 5.1 ± 1.4</td>
</tr>
</tbody>
</table>

**Table 6. Intake and dose assessment methods and tools used by the participating laboratories.**

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Assumptions, methods and tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>DCAL: urinary excretion fraction</td>
</tr>
<tr>
<td></td>
<td>ICRP: ingestion dose coefficient, ‘Reference Man’ (1.6 l urine per day)</td>
</tr>
<tr>
<td></td>
<td>AIDE: for confirmation</td>
</tr>
<tr>
<td>004</td>
<td>ICRP: ‘Reference Man’ (1.6 l urine per day), acute intake, ingestion dose coefficient</td>
</tr>
<tr>
<td>005</td>
<td>ICRP: ‘Reference Man’ (1.6 l urine per day), gastrointestinal (GI) tract model, radiation and tissue weighting factors, reference bioassay and biokinetic models; fI values</td>
</tr>
<tr>
<td></td>
<td>IMBA Professional Plus: acute intake, ingestion, Day 2 sample, intake and dose calculation</td>
</tr>
<tr>
<td>006</td>
<td>A national guideline based on ICRP data</td>
</tr>
<tr>
<td>007</td>
<td>ICRP: ‘Reference Man’ (1.6 l urine per day), gastrointestinal (GI) tract model, radiation and tissue weighting factors, reference bioassay and biokinetic models; fI values</td>
</tr>
<tr>
<td></td>
<td>IMBA Professional Plus: intake and dose calculation</td>
</tr>
<tr>
<td></td>
<td>Other assumption: presence of $^{90}\text{Sr}$ from the decay of $^{90}\text{Y}$ intake</td>
</tr>
<tr>
<td>008</td>
<td>IMBA Professional Plus: intake and dose calculation</td>
</tr>
<tr>
<td>009</td>
<td>ICRP: biokinetic and dosimetric models, Day 2 urine from ‘Reference Man’ (1.6 l urine per day)</td>
</tr>
<tr>
<td></td>
<td>IMBA: intake and dose calculation</td>
</tr>
<tr>
<td></td>
<td>MONDAL: 3; for confirmation</td>
</tr>
</tbody>
</table>

**Table 7. Intake and dose assessment results from participating laboratories.**

<table>
<thead>
<tr>
<th>Lab code</th>
<th>Intake (MBq)</th>
<th>50y CED (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>1.3</td>
<td>270</td>
</tr>
<tr>
<td>004</td>
<td>1.44</td>
<td>297</td>
</tr>
<tr>
<td>005</td>
<td>$^{241}\text{Am}$: 0.22; $^{242}\text{Cm}$: 0.007; $^{239}\text{Th}$: 27; $^{238}\text{Th}$: 92</td>
<td>$^{241}\text{Am}$: 45; $^{242}\text{Cm}$: 0.08</td>
</tr>
<tr>
<td>006</td>
<td>1.53</td>
<td>306</td>
</tr>
<tr>
<td>007</td>
<td>$^{241}\text{Am}$: 1.4; $^{238}\text{Pu}$: 0.006; $^{90}\text{Sr}$: 0.0016; $^{241}\text{Pu}$: 16 (not certain)</td>
<td>$^{241}\text{Am}$: 290; $^{238}\text{Pu}$: 16; $^{90}\text{Sr}$: 0.0044</td>
</tr>
<tr>
<td>008</td>
<td>1.46</td>
<td>300</td>
</tr>
<tr>
<td>009</td>
<td>1.8</td>
<td>360</td>
</tr>
</tbody>
</table>
This person would be a candidate for treatment as the CED is above 250 mSv. However, other parameters than CED should be considered as well. DTPA would be the proper countermeasure.


Treatment is recommended as soon as possible with decoporation agent DTPA by intravenous administration together with the use of binding agents to enhance faecal excretion. Further monitoring of the urinary and faecal excretion to obtain more reliable evaluation on intake and to verify the effectiveness of the treatment.


It is recommended to initiate DTPA treatment immediately as the estimated dose from both Th and Am is within the range to consider intervention. Daily administration of 1 g Ca-DTPA in 100 ml normal saline via drip infusion for the first day, followed by 1 g Zn-DTPA in the following days, is recommended. The termination of treatment should be based on the treatment efficacy monitored by bioassay. Because 1 week has passed since ingestion of these radionuclides, GI tract clearance using laxatives may not be effective. Absorption of these radionuclides from the GI tract is thought to be low. Laxatives such as sorbitol can be the choice to further reduce the absorption.


Treatment with DTPA therapy should be applied immediately as the committed 50y effective dose exceeds 250 mSv and side effects of the treatment are low. However, the risk–benefit assessment must be made by a highly specialised physician. Further incorporation monitoring should be performed.


As the committed 50y effective dose exceeds the action level of 200 mSv recommended by the TMT Handbook, the person should be referred for immediate medical assessment. Treatment with DTPA-Ca and/or DTPA-Zn is suggested. Further monitoring (24-h urine, in vivo measurement of 241Am in the liver and bone over the next 15 d), information gathering (chemical forms, appropriate RBE values for organ dose assessment) and reassessment of organ doses for the individual rather than the Reference Worker using state-of-the-art models (i.e. the ICRP Human Alimentary Tract Model and OIR systemic models) may be considered.


Treatment is recommended with chelation therapy (DTPA-Zn or DTPA-Ca) under the supervision of a qualified physician.


Treatment is recommended with chelation therapy (daily intravenous administration of 1 g of DTPA in 250 ml normal saline. The duration and administration pattern will depend on bioassay results performed every day during the first week.


