ansto radiopharmaceuticals and industrials

PMB 1 Menai NSW 2234, Australia. Telephone General 9717 3111 ABN 47956 969 590

25 November 2008

Dr John Loy
Chief Executive Officer
Australian Radiation Protection and Nuclear Safety Agency
PO Box 655
Miranda NSW 1490

Facility Licence Number F0044-5A
ARPANS Regulation 45(3): Report of a Breach of a Licence Condition

Dear Dr Loy

I refer to facility licence F0044-5A (the "ARI Licence") and, in accordance with ARPANS regulation 45(3), hereby inform you of a technical breach of a licence condition.

Under Schedule 2 of the ARI Licence, ANSTO is permitted to hold up to 54 GBq of Yttrium-90 (^{90}Y) in each of Buildings 23 and Building 23A. On 24 November 2008, during an internal compliance review, ANSTO identified that ARI was holding 294 GBq of ^{90}Y (at calibration).

ARI has undertaken a preliminary investigation of the breach, and it appears that the licence condition regarding the maximum ^{90}Y activity is not compatible with the objective of the licence. That is, the maximum activity levels for ^{90}Y listed in Schedule 2 are not set at a limit consistent with ARI's manufacture of ^{90}Y product. For years prior to the ARI Licence being granted, ARI (Buildings 23 and 23A) was receiving irradiated targets from HIFAR which periodically exceeded 100 GBq of ^{90}Y. Since the shutdown of HIFAR in 2006, ARI has been required to import even higher activity of ^{90}Y

There are no safety issues associated with the increased holdings. ANSTO has been reviewing the operator dose data monthly (EPD and TLD) for the operators working on the ^{90}Y process, and this data indicates that radiation doses have not been elevated as a result of the increased activity in Buildings 23 and 23A. ARI staff have been reminded of the licensed activity limits, and ARI is currently reviewing the control processes for receipt of ^{90}Y within Buildings 23 and 23A.

In order for ANSTO to continue to manufacture ^{90}Y and supply it to the medical community, the ARI Licence will require an increase in the levels of activity of ^{90}Y. Accordingly, ANSTO is in the process of preparing an urgent submission to ARPANSA to request an amendment to the ARI Licence to increase the amount of ^{90}Y that can be held in buildings 23 and 23A.

Yours sincerely

Ian L Turner
General Manager, ARI

S. Ballantyne
Compliance & Quality Manager

cc: CEO, ANSTO
Director Regulatory & Policy, ARPANSA
Government Liaison, ANSTO

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PMB 1 Menai NSW 2234, Australia. Telephone General 9717 3111 ABN 47956 969 590

09 February 2009

Mr Peter Burns
Acting Chief Executive Officer
Australian Radiation Protection and Nuclear Safety Agency
PO Box 655
Miranda NSW 1490

Dear Mr Burns

Facility Licence Number F0044-5A (ARI Licence): Breach of the *Australian Radiation and Protection and Nuclear Safety Regulation 1999* (the ARPANS regulation) - regulation 48

ARI staff recently identified a non-conformance with the *Code of Practice for the Safe Transport of Radioactive Material* (the Code), which concurrently resulted in a breach of the ARI Licence with respect to regulation 48(2)(b) of the ARPANS regulation.

Event

On Sunday, 18 January 2009, ARI shipped a Type A package containing Mo99 within a GENTECH Generator to an interstate customer. On 19 January 2009, ARI was advised by that customer that the GENTECH Generator which ARI had supplied to them contained an amount of activity higher than that which was ordered, and that the generator had a different calibration date than expected.

It was subsequently calculated that, due to an error in the calibration date, the Type A package contained 1016 GBq of Mo99 when it left ARI on Sunday, 18 January 2009, which exceeded the amount for which the package was certified.

Background

ARI's GENTECH Generator is designed to hold 370 GBq of Mo99 at calibration and, when shipped, is contained in a Type A package which is certified to hold up to 600 GBq. The certification of the Type A package was undertaken in accordance with Table 1, Section 4 of the Code which sets out the maximum amount allowable in a Type A package for Molybdenum 99 as being 600GBq.

Prior to sending the package, ARI undertook an assessment of the Transport Index (TI) which was calculated as 2.7, and calculated the surface dose rate as 357.3uSv/hr. Both of those figures comply with the levels established in the relevant international transport regulations; Clause 530 the Code states that the TI cannot exceed 10 for a shipment of this type of package, and Clause 531 of the Code requires the surface dose limit to be below 2mSv/h. As a result, ANSTO considers that there was no additional safety hazard posed during transport of the package.

Investigation

An investigation was undertaken following the event report. This found the cause of the event to be due to the generator being incorrectly calibrated. The generator, which was manufactured on Sunday, 18 January 2009, was calibrated for Thursday, 22 January 2009, instead of being

calibrated for Monday, 19 January 2009. This occurred through a keying error within ARI's inventory system, which resulted from complications stemming following shortages of Mo99 from the previous shipment. As a precautionary measure, 370 GBq generators are usually shipped the day before the calibration date to ensure the product does not breach the Type A package requirements, however in this case it was overlooked. The relevant ARI staff have been made aware this event and the cause, and ARI is currently undertaking a further investigation into how to implement a systems alarm or alert in instances where the product is out of specification.

If you require any additional information regarding this event, please contact Sarah Ballantyne on 9717 3189.

Yours sincerely

Ian L Turner
General Manager, ARI

cc: Rhonda Evans, Director Regulatory and Policy Branch
Senior Adviser, Government Liaison

ansto radiopharmaceuticals and industrials

PMB 1 Menai NSW 2234, Australia. Telephone General 9717 3111 ABN 47956 969 590

03 August 2009

Rhonda Evans
Director, Regulatory and Policy Branch
ARPANSA
PO Box 655
Miranda 1490

Subject: Reporting of non-compliance with Provisions of the Code of Practice for the Safe Transport of Radioactive Material

Dear Ms Evans

The ARPANSA Code of Practice for the Safe Transport of Radioactive Materials contains a number of requirements for the design and use of type A packages. In accordance with those requirements, ANSTO has certified the ANSTO/049 package. The Certificate of Design Approval for that package imposes the following restriction:

> *"The contents must be placed in glass vials which are sealed, capped and checked as per information shown on the assembly drawing."*

On 27 July, 2ml V-bottom Sodium Iodide (^{123}I) Solution contained in five vials that had been bunged (with a rubber stopper) but not crimp capped, were shipped from the NMC site to the Lucas Heights site for final packaging and subsequent delivery to the customers.

The oversight was realised by the operator at NMC soon after the ARI driver picked up the vials and departed from the NMC site. The Lucas Heights staff were immediately alerted, and upon their receipt in Building 23 the vials were isolated, taken inside the hot-cell and crimp capped. The vials and the pots were checked at Lucas Heights and no contamination of the vials or the pots was detected. The vials were always in ARI's control while they were in the 'un-crimped' state.

Although there were no radiological consequences, this event constitutes a non-compliance with our Certificate of Design Approval and the Code of Practice. If you have any questions, please contact me.

Regards

Ian Turner
General Manager, ARI

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Ref: 06/665

11 August 2010

Dr Carl-Magnus Larsson
Chief Executive Officer
ARPANSA
PO Box 655
MIRANDA NSW 1490

Dear Carl-Magnus

Facility Licence F0044-8A – Actinide Suite – Notification of Possible Breach of Regulation 53(1)

As previously communicated to ARPANSA in the April-June 2010 Quarterly Report for the Actinide Suite, and consistent with ARPANS Regulation 45(3), I wish to inform you of a possible breach of a licence condition of Facility Licence F0044-8A ('the licence') for the Actinide Suite. Specifically, the possible breach relates to disposal of an Atomic Absorption Spectrometer (AAS) and compliance with ARPANS Regulation 53(1).

Description

In July 2008, as part of a review of equipment in the Actinide Suite, the Facility Officer identified an AAS unit (Manufacturer – Perkin Elmer; Model – SIMAA 6000; S/N – 3159) as being inoperable and surplus to requirements. The unit was moved to the transit store for storage pending a decision on final disposal. In early July 2010 a decision was made to dispose of the unit, but upon checking with the transit store, it was realised that the equipment had already been transferred to Pickles Auctions, who specialise in resale of second-hand industrial and scientific equipment. On 28 January 2010, the unit had been on-sold to an undisclosed party.

Possible Breach of Licence Condition

Condition 2 of the licence states controlled persons must comply with Part 4, Division 4 of the ARPANS Regulations. Regulation 53(1) requires the licence holder to obtain approval of the CEO of ARPANSA prior to disposal of controlled apparatus. The Safety Analysis Report for the Actinide Suite indicated that the unit was a controlled apparatus, specifically due to inclusion of an induction furnace. This is reflected in Schedule 1 of the licence. As approval was not sought from the CEO of ARPANSA, it appears *prima facie* that disposal of the unit may constitute a breach of ARPANS Regulation 53(1). However, it is noted that there is some uncertainty about whether the unit actually constituted a controlled apparatus, for the following reasons:

1. Magnetic Field Strength

   The manufacturer's specifications indicate that when in operation, the induction furnace is capable of producing a magnetic field strength of 800 mT "inside the furnace". The exposure limits use to determine whether apparatus which electrically generates magnetic fields is controlled apparatus are defined under the *Interim Guidelines on Limits of Exposure to 50/60 Hz electric and magnetic fields* (RHS 30). For occupational exposure, the limit for short-term exposure is 5 mT whole body and 25 mT to the limbs. While the unit was capable of exceeding these levels inside the furnace, there was no indication in the specification as to whether the levels were accessible to persons in the circumstances set out in ARPANS Regulation 4(2)(c). The induction furnace was

enclosed, and it is possible that the design of the unit provided sufficient shielding and distance to ensure that any stray magnetic flux density would have been below the exemption limit.

2. Operability

   As noted above, the unit was disposed of because it was inoperable. In fact, the faulty component of the unit was the induction heater itself, and the unit was therefore not capable of generating any magnetic fields. As such, it did not meet the definition of controlled apparatus in ARPANS Regulation 4(1), as it was not capable of producing non-ionizing radiation that could lead to a person being exposed to radiation levels in excess of the exposure limits mentioned in Schedule 1.

Corrective Actions

Regardless of whether the disposal of the unit in question constitutes a breach, staff from the Actinide Suite and the transit store have been reminded and retrained of the requirement to obtain approval from the CEO of ARPANSA prior to disposing of controlled apparatus. Furthermore, the ANSTO OHSE Management System guide outlining control of licensable sources is being reviewed to ensure that all regulatory requirements are accurately and clearly conveyed. An event report has also been raised for this incident and any further actions recommended from this investigation will be implemented in due course.

If you require any further information regarding this issue, please contact the ANSTO Regulatory Affairs Officer, Mark Alexander, on (02) 9717 907[illegible].

Yours sincerely

Dr Adi Paterson
Chief Executive Officer

cc: Lyndon Edwards – Head – Institute of Materials Engineering
Hefin Griffiths – Manager – Quality, Safety, Environment and Radiation Protection
Steven McIntosh – Senior Policy Advisor
Mark Alexander – Regulatory Affairs Officer

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Ref: ADM095769

1 June 2012

Mr Martin Dwyer
Head, Operations Services
ARPANSA
PO Box 655
MIRANDA 1490

Dear Mr Dwyer,

ANSTO Health – Facility Licence F0044-5A, 5B, 5C – ARPANS Regulation 45(3) – Sm-153 Inventory in Building 23 and 23A

In accordance with Regulation 45(3) of the *Australian Radiation Protection and Nuclear Safety Regulations 1999*, I wish to report a possible technical non-compliance with a licence condition pertaining to Facility Licence F0044-5A, 5B, 5C ('the licence'). This follows notification by phone earlier today.

Incident Details

At approximately 10.00 am on 28 May 2012, ANSTO Health received a batch of Sm-153 from OPAL into Building 23A for production of Quadramet. This batch was measured to have an activity of 257.3 GBq upon receipt into Cell 7 (Room 0097). This batch was subsequently rejected to waste due to an error in the production process.

Given the 46-hour half-life (46 hours), the six day irradiation time and palliative-care use of Sm-153, it is normal procedure to have a second batch irradiated concurrently in case a product is rejected as happened in this case. Accordingly, the second batch for 28 May was transferred to Cell 7 at 12:25 pm. This batch was measured to have an activity of 280.1 GBq upon receipt. Both batches were programed for a calibrated activity of 214 GBq.

Under Schedule 2 of the licence, ANSTO Health is permitted to hold 250 GBq of Sm-153 in each of Building 23 and 23A. Given that both batches were measured to be in excess of this amount on 28 May, this may constitute a technical non-compliance with a licence condition.

While the amount of Sm-153 was above the level stated in the licence condition, it is noted that there were no safety implications associated with this event. Cell 7 is designed to safely manage up to 25 TBq of Mo-99 and no elevated radiation levels were recorded on either area monitors or personnel EPDs as a result of this event. Regardless, an event report was lodged in accordance with standard ANSTO procedure to determine the cause of the incident.

Preliminary Analysis

Noting that a full investigation will be carried out as part of the event reporting process, initial analysis has identified a possible cause of the event. Following the event, the batch records for recent Sm-153 production runs were reviewed. This review revealed that there were three similar events where Sm-153 was received in ANSTO Health from OPAL in excess of 250 GBq:

- 14 May 2012 – 264 GBq received
- 23 April 2012 – 265 GBq received
- 12 March 2012 – 252 GBq received

This increase in activity broadly correlates with the commissioning of the Heavy Water Upgrade System (HWUS) and consequent improvement in the isotopic purity of the heavy water in OPAL. While the irradiation schedule has a conservative allowance for variability in flux, the timing of HWUS commissioning appears to correlate with the increased activity seen in Sm-153. This will be reviewed during the event investigation process. It is noted that due to the canning process for Sm-153, the activity of the target cannot be specifically measured until it is opened in Building 23A.

Update of Facility Licence

As previously indicated to ARPANSA, ANSTO believes that the structure of the ANSTO Health licence with isotope specific limits is out-dated and needs to be brought into the same format as that for other facility licences held by ANSTO. Many of the isotope limits that are currently imposed by the licence – including that for Sm-153 – reflect operational conditions when the licence was issued in 2002 rather than any safety limit. This has on occasion lead to technical non-compliance with licence conditions with no degradation to safety. The current event would appear to be another case of this anomaly.

I understand from recent discussions between ANSTO and ARPANSA officers that ARPANSA have commenced work on updating the ANSTO Health licence to the same format as other licences held by ANSTO and that this process may include removal of the arbitrary isotope limits. I strongly encourage this approach as it will prevent occurrences of technical non-compliance that have no impact on safety. ANSTO Health will of course assist ARPANSA officers as requested during this process.

If you require any further information regarding this matter, please contact the ANSTO Regulatory Affairs Officer, Mark Alexander, on (02) 9717 9077 or via email at mark.alexander@ansto.gov.au.

Yours Sincerely,

Shaun Jenkinson
General Manager – Commercial Operations

cc: Adi Paterson – Chief Executive Officer
Karen Wolfe – Safety Manager – ANSTO Health
Carlos Chanlin – Production Manager – ANSTO Health
David Vittorio – OPAL Reactor Manager
Helen Griffiths – General Manager – Safety, Environmental and Radiological Assurance
Mark Alexander – Regulatory Affairs Officer

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3 October 2012

Mr Martin Dwyer
Head, Operations Services
ARPANSA
PO Box 655
MIRANDA NSW 1490

Dear Mr Dwyer.

ANSTO Health – Facility Licence F0044-5A, 5B, 5C – ARPANS Regulation 45 (3) – Iodine -131 Inventory in Building 23A

In accordance with Regulation 45(3) of the *Australian Radiation Protection and Nuclear Safety Regulations 1999,* I wish to report a technical non-compliance with a licence condition pertaining to Facility Licence F0044-5A, 5B, 5C. This follows notification of the incident by email on the 3rd October 2012 (Wigney to Scott)

Incident Details

At approximately 1.25pm on 1st October 2012, after running the furnace for I-131 production, operators measured the stock and calculated the yield for the day. It was determined that the yield was 2193GBq. ANSTO Health's current licence permits ANSTO to hold up to 2.035TBq I-131 activity (reference S2009/00010 – Letter dated 28.01.09 from Dr Peter Burns of ARPANSA to Dr Ron Cameron of ANSTO). As a result, the I-131 yield breached the maximum allowable holdings of 2.035TBq.

While the amount of I-131 was above the level permitted in the licence condition, it is noted that there were no safety implications associated with this event.

The I-131 solution is retained in sealed containers and held in-cell. There were no elevated dose readings for staff and no increased stack emissions associated with this event. I-131 holding was within licence limits in 24 hours following decay. An event report has been lodged in accordance with normal ANSTO procedure. Please find a copy of the event report enclosed with this letter.

Preliminary Analyses

Noting that a full investigation will be carried out as per the event reporting process, initial analyses has identified a possible cause of the event. The increase in activity is thought to be related to the improvement in the isotopic purity of the OPAL heavy water. This will be reviewed during the event investigation process.

Update of Facility Licence

As previously indicated to ARPANSA, ANSTO believes that the structure of the ANSTO Health licence with isotope specific limits is out-dated and needs to be brought into the same format as the other facility licences held by ANSTO. Many of the isotope limits that are currently imposed by the licence – including that for I-131- reflect operational conditions when the licence was issued in 2002 rather than any safety limit. This has on occasion led to technical non- compliance with licence conditions with no degradation to safety. The current

event would appear to be another case of this anomaly. ANSTO submitted a licence request to ARPANSA on 10th September 2012 to facilitate the work that ARPANSA is doing to update the ANSTO Health licence into the same format as other licences held by ANSTO and to remove arbitrary isotope limits. ANSTO continue to work with ARPANSA throughout this process

If you require any further information regarding this matter please contact ANSTO Regulatory Affairs Officer, Francesca Wigney, on (02) 9717 3754 or via email at Francesca.wigney@ansto.gov.au.

Yours sincerely,

Shaun Jenkinson
General Manager
Commercial Operations

WIGNEY, Francesca

From: IT Servicedesk
Sent: Monday, 1 October 2012 3:07 PM
To: WOLFE, Karen
Subject: Event Notification - Event Number 52965

Event Notification Email

An event has been lodged by personnel from your division. This message is to notify you of the occurence

Event Number: 52965

Raised By: Roman VEKSELSTEIN

Location of Event: Building 23A, room 0097, Cellface, Cells 2 & 4

Date and Time of the Event:: 1/10/2012 1:25:00 PM

1. What did or could have occurred? (Event description - what, where, when, how, did SOSS attend, etc? - please write as a story\narrative) : After running the Furnace, measuring the stock and calculating the yield for the day it was determined that the facility had 2193 GBq (Facility Limit 2035 GBq). Refer to ARPANSA Quote: S2009/00010

2. Describe action taken immediately as a result of the event?: Production Manager was informed & this infra filed for record of internal limits.
There is no risk to staff or public as the materials are in-cell and in sealed containers.

3. Other information you think is important for us to assess the Incident and reduce the risk of re-occurrence: The material is secured in Cells 2 & 4 for manufacturing use as follows:
Sodium Iodide (I131) Unstabilised Stock (M) 1000137, (B) 129638
Sodium Iodide (I131I) Stabilised Solution Bulk (M) 1000138, (B) 129639
Sodium Iodide (I131) Unstabilised Stock (M) 1000137, (B) 129598
Sodium Iodide (I131I) Stabilised Solution Bulk (M) 1000138, (B) 129599
Sodium Iodide (I131I) Stabilised Solution Bulk (M) 1000138, (B) 129593
Sodium Iodide [I-131] Stabilised Stock 5 GBq/mL - Therapy Capsules (M) 1000141, (B) 129595
Sodium Iodide [I-131] Stabalised Stock 50GBq/mL-Therapy Capsules (M) 1000142, (B) 129640
Sodium Iodide [I-131] Stabalised Stock 50GBq/mL-Therapy Capsules (M) 1000142, (B) 129594
Sodium Iodide [I-131] Stabilised Stock 200 MBq/mL-Therapy Solution (M) 1000143, (B) 129596
Sodium Iodide [I-131] Stabalised Stock 2GBq/mL-Therapy Solution (M) 1000144, (B) 129597

Names of People Involved: Enzo Valente
Contact Telephone Number (if known ie: mobile of contractor): Radiological Facility: No
Offsite Medical Treatment: No
OHS: No

Plant & Equipment:

Abnormal Occurrence: Yes

Environmental Issue: No

Supervisor: Enzo VALENTE**Nominated Individual:**

Australian Government

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Ref: AH301213

Mr Martin Dwyer
Head, Operations Services
ARPANSA
PO Box 655
MIRANDA NSW 1490

30 December 2013

Dear Mr Dwyer,

ANSTO Health – Facility Licence F0044-5A, 5B, 5C – ARPANSA Regulation 45 (3) – Sodium Iodide (I-131) Inventory in Building 23A

In accordance with Regulation 45(3) of the Australian Radiation Protection and Nuclear Safety Regulations 1999, ANSTO would like to report a potential non-compliance with a licence condition pertaining to Facility Licence F004-5A, 5B, 5C ('the licence').

Incident Details

On 30.12.2013, the I-131 activity in Building 23 of the ANSTO Health facility was measured to be 3200GBq (calibrated for 900hrs on 30.12.13); this value was above the 2035GBq level stated under Schedule 2 of the ANSTO Health's ARPANSA licence.

Measured I-131 activity of 3200GBq was stored in Cells 2 (800GBq) and 4 (2400GBq) respectively.

While the amount of I-131 was above the level stated in the licence condition, it is noted that there were no safety implications associated with this event. No elevated radiation results were recorded on either area monitors or personnel EPDs as a result of the event.

In accordance with standard ANSTO procedures an event report was raised for this occurrence.

It is noted that after the completion of the I-131 products manufacture on 30.12.2013 (1400hrs), the left over I-131 activity was 2320GBq (calibrated for 900hrs on 30.12.13);.

Customer Demand for I-131 and the Production Yield

As a result of recent concurrent shut down of a number of nuclear reactors worldwide, ANSTO Health has been producing additional batches of I-131 to meet the customer demand. Also the yield from I-131 batch manufactured on 30.12.13 was much higher than expected (expected yield was 80% of the theoretical yield, actual yield from the batch was 111% of the theoretical; possibly due to target position in the OPAL reactor). These factors contributed to the exceedance of the licenced I-131 activity.

Update of the Facility Licence

To cater for the changing product offerings by ANSTO Health and to meet the required operational requirements, ANSTO on 11 September 2013 submitted an application to ARPANSA for update of the facility licence. In this application, request was made to increase the facility holdings limit for I-131 to 6000GBq and for an increase in individual cell holding limits for I-131 to 3000GBq. Safety case justification was provided for the requested values. As per the Microshield calculations for Cells 2, 4 and 5, these cells were shown to provide adequate radiation shielding to I-131 activities of up to 19000GBq (Cell 2) , 19000GBq (Cell 3) and 5665000GBq (Cell 5) respectively. I-131 values measured on 30.12.13 were lower than those requested in this licence update.

If your staff require any further information regarding this matter, please contact Aman Sharma on (02) 97173216 or via email at Amandeep.sharma@ansto.gov.au

Yours Sincerely,

Shaun Jenkinson
Group Executive, Nuclear Business

Encl: Copy of event report

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2 August 2016

Mr Jack Dillich
Head of Regulatory Services Branch and Chief Inspector
ARPANSA
PO Box 655
MIRANDA NSW 1490

Dear Mr Dillich

HIFAR F0184 – Regulation 45 (3) non-compliance to Operating Limits and Conditions.

In accordance with Regulation 45(3) of the *Australian Radiation Protection and Nuclear Safety Regulations 1999*, ANSTO would like to report a potential non-compliance with operating limits and conditions (OLC's) for the HIFAR Possess or Control Licence F0184. This follows notification by email (P. Berghofer to J. Ward, May 16).

Incident Details
In preparation for an upcoming inspection, ARPANSA Officer John Ward requested a copy of HIFAR Procedure NHP 9.2.22 – Control of Hazardous Materials, which is referenced in HIFAR OLC 3.5. In locating this procedure, it appeared to not be a current document in the HIFAR Quality Management System (QMS).

During investigation of this matter it was separately identified that a potential breach of an OLC surveillance requirement was not formally investigated or reported at the time of identification (December 2015), although a process was implemented to rectify the issue.

Investigation Findings
Regarding HIFAR Procedure *NHP 9.2.22 – Control of Hazardous Materials*, the investigation found that the procedure had been removed from the QMS following the shutdown of the reactor; however the requirements of this procedure were alternatively captured under the HIFAR Procedure *Conduct of Activities in the HIFAR Facility (NHP1.15)*. It was subsequently identified that there were however failures to obtain written permission from the Facility Officer when taking hazardous materials into Building 15 as is required by Limiting Condition (3.5.3);

"Administrative controls shall be placed on the entry of all flammable and explosive, materials into Building 15. Such materials shall not be taken into Building 15 without the written permission of the Facility Officer."

Regarding the second matter it was identified that the Radiation monitors continued to not be tested every 3 months as required by the OLC despite the issue being identified in December 2015 and a work order raised in SAP to address the non-conformance. Additionally the event was not investigated and notified to ARPANSA as per the requirements of Regulation 45.

Please find investigation reports attached. The HIFAR Safety Analysis Report and OLCs are currently undergoing review and it is anticipated that changes will be requested to align these document to current standards. In the meantime, actions have been identified to prevent reoccurrence of the reported issues.

If you require any further information regarding this matter please contact the Manager, Regulatory Affairs Paula Berghofer on 9717 3754 or paula.berghofer@ansto.gov.au

Yours Sincerely,

Duncan Kemp
Acting Head of Nuclear Services & Chief Nuclear Officer

AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION
New Illawarra Road, Lucas Heights (Locked Bag 2001, Kirrawee DC 2232) T +61 2 9717 3111 F +61 2 9717 9210
www.ansto.gov.au

From: Jim Scott
To: BERGHOFER, Paula
Cc: Vaz Mottl; Andrew Wulf; SENIOR, Jayne; MOORE, Mark; SHARMA, Amandeep; ARKAPAW, Samantha; $ARPANSA Licence Administration
Subject: RE: Notification of Potential Breach - ANSTO Health Building 23 Licence F0262 [SEC=UNCLASSIFIED]
Date: Thursday, 3 May 2018 12:50:55 PM
Attachments: image001.png

Hi Paula

Many thanks.

We will await your investigation.

I understand Andrew Wulf will undertake a site visit early next week, in which case he can ensure that there are no immediate safety implications. However yon informed me at our meeting yesterday that the process has been suspended in the meantime, in which case there are no immediate safety issues.

Regards
Jim Scott

Jim Scott
Branch Head
Regulatory Services
ARPANSA

Australian Radiation Protection and Nuclear Safety Agency
Phone: +61 2 9541 8343
Mob: +61 419 793 341
Email: jim.scott@arpansa.gov.au
http://www.arpansa.gov.au

From: BERGHOFER, Paula <pbz@ansto.gov.au>
Sent: Thursday, 3 May 2018 12:31 PM
To: Jim Scott <Jim.Scott@arpansa gov.au>
Cc: Vaz Mottl <Vaz.Mottl@arpansa.gov.au>; Andrew Wulf <andrew.wulf@arpansa gov.au>; SENIOR, Jayne <jaynes@ansto.gov.au>; MOORE, Mark <mmx@ansto.gov au>; SHARMA, Amandeep <ash@ansto.gov.au>; ARKAPAW, Samantha <sja@ansto.gov au>
Subject: Notification of Potential Breach - ANSTO Health Building 23 Licence F0262 [DLM=For-Official-Use-Only]

Dear Jim,

As discussed when we met yesterday, an incident has been raised at ANSTO Health that suggests potential non-compliance with the requirements of ARPANS Regulation 51.

This is in relation to the submission currently being assessed by ARPANSA that is requesting to make changes to the I-123 MIBG process in Building 23 under Facility Licence F0262.

We are currently investigating this matter in accordance with our internal processes and will provide further advice on completion of this. The initial event notification that was raised yesterday is copied below for information.

In the meantime if you would like any further information please don't hesitate to contact me.

Kind Regards,
Paula

From: grc8support@ansto.gov.au [mailto:grc8support@ansto.gov.au]
Sent: Wednesday, 2 May 2018 4:00 PM
To: BERGHOFER, Paula
Subject: GRC Cloud Action Required Workflow Summary

Dear BERGHOFER, Paula,

WHS Incident Notification

This email is for your information only as the Health & Safety Representative or other relevant stakeholder.

An Incident has occurred. You can view the information attached. If you require further information please contact the Triage Officer directly.

For assistance with GRC Cloud please contact the IT HelpDesk on x9200.

Assess items in the GRC Cloud Assessor

				Describe	Other					

Item #	Item Name	Date of the Incident	Detailed Description of Incident	action/s taken immediately as a result of the Incident	information you think is important for us to assess the Incident	#Logged By Division / Platform	Actual Impact Rating (triage)	Potential Impact Rating (triage)	Triage Officer Comments	Assigned Triage Officer
4598	Submitted by Russell C THIERING - Wednesday May 2 2018 11:31 AM	2/05/2018	Reference SAC Submission: 2087 During preparation of responses to ARPANSA, in relation to I-123 submission, it was noted that there may have been misunderstanding in relation to the scope of the change. This requires clarification. Immediate actions taken were: a) to contact P Berghofer as the ARPANSA liaison, and b) ask S Arkapaw to review the state of the submission package.	Immediate actions taken were: a) to contact P Berghofer as the ARPANSA liaison, and b) ask S Arkapaw to review the state of the submission package.			Moderate	Moderate	SP 2/5/18 11.45am- spoke to incident logger regarding incident details. investigator to be S. Arkapaw	PAN, Am, Shilpa

Thank You,
GRC Cloud Administrator