PS Minute for case: 2018/0016281

This follows two previous letters received on this matter from Alex Neil. Those letters, and our replies, are attached as an annex here.

The Health Board has provided further information, as copied out below, and this has been used as the basis of this reply.

Latest information from Health Board (provided by [REDACTED – PERSONAL INFORMATION (S38(1)(B)], General Manager, Facilities and Estates):

Regarding the suggested inconsistency between prior communications, we report and review all adverse events. Where required by our standards, we also conduct a formal investigation. I am aware of the previous accusations of 'safety breaches' by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and we have been clear throughout that all potential patent-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact which we believe was suggested by [REDACTED – PERSONAL INFORMATION (S38(1)(B)].

The adverse events [REDACTED – PERSONAL INFORMATION (S38(1)(B)] refers to were reported to Incident Reporting and Investigation Centre (IRIC) (as they always are) and as appropriate these were investigated by a multi-disciplinary team including HFS specialist input. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. I am not sure what issue [REDACTED – PERSONAL INFORMATION (S38(1)(B)] believes has not been rectified, as he has raised numerous concerns in his various communications.

As you know, we have very recently (on Tuesday 15th May) had the decontamination 'expert' team from Health Facilities Scotland (HFS) review the management of the issues raised to by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and also our current service arrangements. This was primarily in response to [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s numerous and continuing wide-ranging challenges. We await the written report from HFS but the verbal feedback from them was that that they support the previous investigation outcomes which indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] was very low indeed.

With regard to two different systems being in place. All areas of NHS Grampian operate to the same national NHS Decontamination Standards and the NHSG governance structure covers all locations. The operational arrangements to deliver the service will differ between locations for good reason. For example, in Aberdeen we have an established Decontamination Service, separate to the clinical teams. This is an appropriate arrangement given of the scale of the activities concentrated around Aberdeen as a city. By contrast, at Dr Gray's Hospital in Elgin where the level of activity is much lower, the decontamination team is integrated within the clinical team.

We use specialist decontamination equipment contractors, including Medical Devices UK, where we don't have the in-house competence and/or where this is best value for NHS Grampian. We have an ongoing contract with Medical Devices UK for the periodic validation of our automatic endoscope re-processors in Aberdeen and there is no plan to change this. There is a separate ongoing contract for the same type of work in Dr Gray's Hospital in Elgin. We have maintenance contracts with other specialist companies for different types of equipment, commonly with the original equipment manufacturer or supplier.

We previously had a contract with Medical Devices UK for the maintenance and testing of our endoscope storage cabinets in Aberdeen. We have made a decision to transition this work in-house in a controlled way. This provides both a technically competent solution and much better value for NHSG. This type of work is still out-sourced to Medical Devices UK for Dr Gray's Hospital in Elgin.

As with [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s suggestions on patent safety breaches, the team from HFS reviewed our current service arrangements on 15th May. HFS have verbally indicated their satisfaction with what we are doing and we expect this to be confirmed in the written report when it is issued.

Our relationship with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and therefore Medical Devices UK is becoming increasingly difficult. As you are aware, we did offer to meet him personally on Monday 14th May together with our local service manager to see how best to move forward. The local management team were understandably cautious, given the wide range of issued raised and that these have been escalated quickly through different routes. However, [REDACTED – PERSONAL INFORMATION (S38(1)(B)] later declined the offer, saying he did not want to meet without a formal agenda and representation. In the meantime, staff from Medical Devices UK have been on site this week doing their normal work.

We plan to repeat the offer of a structured meeting to try to better understand his core concerns and how a viable supplier relationship might be re-established and sustained.

Finally, it is very unfortunate that these are being raised in this way as part of our contractual service relationship, which instead should have been highlighted through the course of any service visits to our sites. What is interesting here, is that these issue are now only being raised following the changes to our revised service model requirements with Medical Devices UK and elements which were previously serviced by Medical Devices UK are now being delivered in-house.

Alex Neil Email of 22 March (and reply):

From: Neil A (Alex), MSP [mailto:Alex.Neil.msp@parliament.scot]
Sent: 22 March 2018 08:50
To: Cabinet Secretary for Health and Sport
Subject: FW: Ref - 2018/0006670
Importance: High
Dear Shona
Many thanks for your reply to me dated 21st March regarding decontamination services in NHS Grampian
I have shared your response with my constituent, who wishes to remain anonymous
Please find attached his comments
I would appreciate you giving detailed consideration to each of the points and advice accordingly
Meantime I look forward to hearing from you
Yours sincerely
Alex Neil MSP

Hi Alex,
Thank you for forwarding over the response from Shona Robinson.
I would like to make some comments in response to the letter received.
Paragraph 1
Arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.
All trusts agreed to sign up to a national contract to achieve best value from suppliers awarded national contracts,
All suppliers where asked to fix pricing throughout the framework period to enable the trust to budget.
This framework has now been extended for 25 months to allow national procurement to evaluate cost savings and publish a new framework agreement; suppliers again being ask to fix prices this would be a price fix for 5 years in total.
When the hospital wants to transition to in-house for best value this can only be achieved when the persons carrying out the work have the correct skill set qualifications and are changing out the stipulated components at each service interval. Otherwise the risk to patient safety is being compromised by cost for which budgets had been set aside, the criteria tendered for on the national contract from the OJEU is not being carried out in accordance with the minimum requirements and to the standard BS EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.
Paragraph 2
Whilst the transition is underway, the service has engaged appropriate short - term training and support from a third party company who have the necessary qualifications and expertise to provide this. The health board confirm that this has been done in full compliance with the requirements of NHS Scotland framework contract, as confirmed with the relevant commodity manager at NHS procurement.
How long will the transition period be as the machines are still in use without a proper validation being performed?
The third party company who is providing the training to in-house staff has no

manufacturer equipment experience, not approved by NHS framework or the OJEU for maintenance & testing of any Medical Device, it has never had to produce public liabilities insurance to the sum of £10,000,000 or never met the minimum requirements of the OJEU for quality management system ISO 9001: 2015 this is costs that all small companies have to endure to set up these systems to meet the basic requirement to apply for the national contracts.
Have we ignored the minimum requirements and risked patient safety?
What is the best value of using a non-approved contractor who has none of the above?
While we accept it is NHS Grampians decision to whom they allow to work on there equipment I must call to action the rational behind this decision on allowing an unqualified company to train unqualified personnel with no electrical, mechanical or electronic background to service and test medical equipment for use in patients.
NHS has a policy of any person working on equipment must be employed by estates department with a minimum 5 years electrical, mechanical trade experience before you can apply for a job as a band 5 test person.
The individuals being trained to carryout this work, have no such skill set and the jobs have never been advertised to persons with the relevant qualifications
Is this a question for HSE or Trade unions?
What is the value of the work being contracted out to the third party company should this have gone out to public tender?
This is an off contract spend surely this had to be carried out under a mini tender process at least.
Can the company providing the training assist with the health board providing a sample test report for the validation work undertaken that meets the requirements of the OJEU National procurements tender qualification envelope.
This should include but not limited to Manufacturers Certification of competency, Certification of all service components used on the service & revalidation of the equipment, Certification of all test equipment used to record the data along with current calibration certificates for all equipment.
Recorded in a document that is acceptable for the requirements.
Once this has been verified that all the requirements have been met then this could prove to be best value.
If all parameters are not met then we do not have a level playing field?
Are the national contracts worth the effort put in to become an approved supplier?

Paragraph 3

The most recent audit took place in February, with the outcome being a recommendation for the continuation of the certification.
The audit was carried out for a second time within the endoscopy unit due to the failings identified within the endoscopy department in the previous audit.
The unit had to report an incident to MHRA for the use of non-validated chemicals being inserted into machines to perform high-level disinfection processes on endoscopes for use in patients in June 2017 and a subsequent IRIC investigation took place and found the unit at fault for all matters concerned.
After this investigation was completed the unit then proceeded to do this 2 further times but choose to ignore the incidents.
The head of decontamination, the decontamination manager, quality & safety manager, Health facilities Scotland authorising engineer where all informed but all choose not to respond.
Email chain can be provided.

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
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EH99 1SP

Our ref: 2018/0009997
April 2018

I am grateful for your further letter in connection with decontamination services within NHS Grampian.

Managers of the decontamination services at NHS Grampian are fully aware of the technical requirements of the work in question, and have given reassurances that they will not compromise on those. The Health Board is investing in the skill-set of in-house staff and is confident that staff will achieve the required certification as planned.

As I stated in my previous letter, NHS Grampian has contracted a suitably qualified and experienced third-party to provide interim support, where required, during the transition period. The Health Board confirms that these arrangements are in full compliance with the NHS Scotland framework, as agreed by the relevant commodity manager at NHS National Procurement.

Finally, in relation to the BSI audit, the Health Board again states that this was carried out in February 2018 and continuing certification has been confirmed. The Health Board has also provided reassurance that it routinely reports all potentially adverse incidents to the Incident Reporting and Investigating Centre as standard, and these are further reported to the Medicines and Healthcare Products Regulatory Agency where appropriate. The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated, and concluded satisfactorily.

I hope this is helpful.

SHONA ROBISON

Alex Neil Email of 21 February (and reply):

From: Neil A (Alex), MSP [mailto:Alex.Neil.msp@parliament.scot]
Sent: 21 February 2018 10:13
To: Cabinet Secretary for Health and Sport
Subject: NHSS National Framework Contract for Decontamination Devices-Grampian NHS
Importance: High

Dear Shona

I have been asked by one of my constituents, who wishes to remain anonymous, to bring the following situation to your attention, as it presents a potential risk to patient safety in NHS Grampian

Despite there being an NHSS National Framework Contract for Decontamination Devices it appears that the Head of Decontamination within NHS Grampian has stopped using these approved contractors for certain devices.

For example a company which isn't a Framework contractor has been brought in provide endoscope storage cabinets and apparently safety requirements are being flouted.

For example: the new company apparently does not possess an appropriate certification; safety features are being overridden; there is a question mark over whether it has the necessary indemnity insurance for the work it is doing; as well as a question mark over whether the service components are being changed every 6 months as they are required to be to protect patient safety/desiccant filter issues.

I am informed that there have been 4 safety breaches in Aberdeen Royal Infirmary Endoscopy Department since this company took over the contract, including a failed BSI audit.

Clearly if these allegations are true then urgent action is needed to investigate why a non-Framework contractor is being used and what action now needs to be taken to ensure that patient safety is not being compromised.

Meantime I would appreciate it if you could please advise your response

In appreciation

Yours sincerely

Alex Neil MSP

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
EDINBURGH
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Our ref: 2018/0006670
March 2018

Thank you for your email of 21 February concerning decontamination services at NHS Grampian.

The Health Board has confirmed that its decontamination service abides by the arrangements put in place by NHS National Procurement with regard to the NHS Scotland National Framework Contract for Decontamination Services. I understand that, at present, the Health Board does not have a service contract in place for the testing and validation of endoscopy service cabinets with a framework contractor. Instead, arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.

Whilst the transition is underway, the service has engaged appropriate short-term training and support from a third party company who have the necessary qualifications and expertise to provide this. The Health Board confirms that this has been done in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the BSI Audit, NHS Grampian confirms that its decontamination service holds certification to BS EN ISO 13485 for all areas, and has never failed an audit. The most recent audit took place in February, with the outcome being a recommendation for the continuation of certification.

Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department, the Health Board advises that no such incidents have been reported.

I hope this is helpful.

SHONA ROBISON

PS MINUTE FOR CASE 2018/0024778

This is the latest in a short series of letters received on behalf of Medical Devices UK.

NHS Grampian have taken a decision to move to in-house decontamination services, with Medical Devices UK gaining less business from the Health Board as a result.

The Health Board met with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] in June because it considers its relationship with Medical Devices UK to have become increasingly unsatisfactory, partly linked to NHS Grampian's reduced spend with that supplier and also its attempts to address a number of contract performance issues. [REDACTED – PERSONAL INFORMATION (S38(1)(B)] has made many and varied allegations though several routes to NHS Grampian, all of which the Health Board believes have been addressed thoroughly and satisfactorily.

Previous correspondence is attached here.

Correspondence with Alex Neil, February 2018

From: Neil A (Alex), MSP [mailto:Alex.Neil.msp@parliament.scot]
Sent: 21 February 2018 10:13
To: Cabinet Secretary for Health and Sport
Subject: NHSS National Framework Contract for Decontamination Devices-Grampian NHS
Importance: High

Dear Shona

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Meantime I would appreciate it if you could please advise your response

In appreciation

Yours sincerely

Alex Neil MSP

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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0006670
March 2018

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Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department, the Health Board advises that no such incidents have been reported.

I hope this is helpful.

SHONA ROBISON

Correspondence with Alex Neil, March 2018

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****
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contract from the OJEU is not being carried out in accordance with the minimum requirements and to the standard BS EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.

Paragraph 2

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How long will the transition period be as the machines are still in use without a proper validation being performed?

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The individuals being trained to carryout this work, have no such skill set and the jobs have never been advertised to persons with the relevant qualifications

Is this a question for HSE or Trade unions?

What is the value of the work being contracted out to the third party company should this have gone out to public tender?

This is an off contract spend surely this had to be carried out under a mini tender process at least.

Can the company providing the training assist with the health board providing a sample test report for the validation work undertaken that meets the requirements of the OJEU National procurements tender qualification envelope.

This should include but not limited to Manufacturers Certification of competency, Certification of all service components used on the service & revalidation of the equipment, Certification of all test equipment used to record the data along with current calibration certificates for all equipment.

Recorded in a document that is acceptable for the requirements.

Once this has been verified that all the requirements have been met then this could prove to be best value.

If all parameters are not met then we do not have a level playing field?

Are the national contracts worth the effort put in to become an approved

supplier?

Paragraph 3

The most recent audit took place in February, with the outcome being a recommendation for the continuation of the certification.

The audit was carried out for a second time within the endoscopy unit due to the failings identified within the endoscopy department in the previous audit.

The unit had to report an incident to MHRA for the use of non-validated chemicals being inserted into machines to perform high-level disinfection processes on endoscopes for use in patients in June 2017 and a subsequent IRIC investigation took place and found the unit at fault for all matters concerned.

After this investigation was completed the unit then proceeded to do this 2 further times but choose to ignore the incidents.

The head of decontamination, the decontamination manager, quality & safety manager, Health facilities Scotland authorising engineer where all informed but all choose not to respond.

Email chain can be provided.

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0009997
April 2018

I am grateful for your further letter in connection with decontamination services within NHS Grampian.

Managers of the decontamination services at NHS Grampian are fully aware of the technical requirements of the work in question, and have given reassurances that they will not compromise on those. The Health Board is investing in the skill-set of in-house staff and is confident that staff will achieve the required certification as planned.

As I stated in my previous letter, NHS Grampian has contracted a suitably qualified and experienced third-party to provide interim support, where required, during the transition period. The Health Board confirms that these arrangements are in full compliance with the NHS Scotland framework, as agreed by the relevant commodity manager at NHS National Procurement.

Finally, in relation to the BSI audit, the Health Board again states that this was carried out in February 2018 and continuing certification has been confirmed. The Health Board has also provided reassurance that it routinely reports all potentially adverse incidents to the Incident Reporting and Investigating Centre as standard, and these are further reported to the Medicines and Healthcare Products Regulatory Agency where appropriate. The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated, and concluded satisfactorily.

I hope this is helpful.

SHONA ROBISON

Correspondence with John Swinney, May 2018

From: Swinney J (John), MSP [mailto:John.Swinney.msp@parliament.scot]
Sent: 17 May 2018 10:04
To: Deputy First Minister and Cabinet Secretary for Education and Skills
Subject: Medical Devices U.K.
Could you please pass this to Ms Robisons's Ministerial Office.
Thanks.
J
Dear Shona,
Medical Devices UK
I refer to our conversation on Tuesday regarding the concerns of Medical Devices U.K., a company based in my Constituency, regarding their contractual arrangements with NHS Grampian.
Medical Devices U.K. provides an independent testing and validation service for decontamination facilities of a medical device. The scheduled testing programme is to assess that the equipment is operating to the defined parameters of the commissioning data recorded at the time of the installation process. The company provides these services at Aberdeen Royal Infirmary and at other NHS sites through a framework contract that has brought savings to the NHS.
In both September 2017 and February 2018 the company identified potential patient safety risks due to changes to the processes for cleaning equipment to ensure effective decontamination. I understand that the event in September 2017 was rectified but the event in February 2018 May not have been.
This issue has been raised by the company through Alex Neil MSP with whom you corresponded on 21 March and 24 April. The company point out that in your letter of 21 March, you state :
"Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department,the Health Board advises that no such incidents have been reported."
In your letter of 24 April, the company point out that you state :
"The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated and concluded satisfactorily."
The company make the point that there appears to be a contradiction between these two statements. In addition, they make the point that they do not believe the statement quoted from your letter of 24 April to be accurate as they believe not all of the incidents have been rectified.
The company have raised these concerns - as they are contractually bound to do - and now find that they are no longer to be used by Aberdeen Royal Infirmary to provide these validation services.
I would be grateful if these concerns could be looked into with vigour to provide clarity for my constituents.
I look forward to hearing from you.
Yours sincerely,
John
John Swinney
MSP for Perthshire North

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr John Swinney MSP
The Scottish Parliament
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Our ref: 2018/0016281
13 June 2018

Dear John,

Thank you for your email of 17 May concerning Medical Devices UK and decontamination services within NHS Grampian.

As you are aware, I have previously corresponded with Alex Neil on this issue and, in light of the concerns raised by Mr Neil, the Health Board confirmed that it is making arrangements for the in-house provision of decontamination services and is doing so in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the suggested inconsistency concerning potential safety breaches or adverse events, the Health Board confirms that it reports and reviews all adverse events and, where required, also conducts a formal investigation. The Health Board is aware of [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s concerns, but has been clear throughout that all potential patient-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact of a type that the Health Board understands was suggested by [REDACTED – PERSONAL INFORMATION (S38(1)(B)].

The adverse events that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] has referred to were reported to Incident Reporting and Investigation Centre (as per standard procedure) and, as appropriate, these were investigated by a multi-disciplinary team that included input from Health Facilities Scotland. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. With respect to issues that [REDACTED – PERSONAL

INFORMATION (S38(1)(B)] believes have not been rectified, the Health Board is unclear as to what is being referred to.

On 15 May the Health Board had a decontamination expert team from Health Facilities Scotland review the management of the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and also our current service arrangements. This was primarily in response to [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s continuing challenges. Whilst the Health Board awaits the written report from Health Facilities Scotland, verbal feedback was that that they support the previous investigation outcomes which indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] was very low indeed.

I am aware that the Health Board offered to meet [REDACTED – PERSONAL INFORMATION (S38(1)(B)] on 14 May in order to attempt to move forward from the present situation, though I understand that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] subsequently declined the offer. The Health Board confirms that it plans to repeat the offer of a structured meeting to try to better understand [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s position, and explore how a viable supplier relationship might be re-established and sustained, and I would hope that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] feels in a position to accept the offer.

SHONA ROBISON

Cabinet Secretary for Health and Sport
Shona Robison MSP

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As you are aware, I have previously corresponded with Alex Neil on this issue and, in light of the concerns raised by Mr Neil, the Health Board confirmed that it is making arrangements for the in-house provision of decontamination services and is doing so in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the suggested inconsistency concerning potential safety breaches or adverse events, the Health Board confirms that it reports and reviews all adverse events and, where required, also conducts a formal investigation. The Health Board is aware of [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s concerns, but has been clear throughout that all potential patient-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact of a type that the Health Board understands was suggested by [REDACTED – PERSONAL INFORMATION (S38(1)(B)].

The adverse events that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] has referred to were reported to Incident Reporting and Investigation Centre (as per standard procedure) and, as appropriate, these were investigated by a multi-disciplinary team that included input from Health Facilities Scotland. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. With respect to issues that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] believes have not been rectified, the Health Board is unclear as to what is being referred to.

On 15 May the Health Board had a decontamination expert team from Health Facilities Scotland review the management of the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and also our current service arrangements. This was primarily

in response to [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s continuing challenges. Whilst the Health Board awaits the written report from Health Facilities Scotland, verbal feedback was that that they support the previous investigation outcomes which indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] was very low indeed.

I am aware that the Health Board offered to meet [REDACTED – PERSONAL INFORMATION (S38(1)(B)] on 14 May in order to attempt to move forward from the present situation, though I understand that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] subsequently declined the offer. The Health Board confirms that it plans to repeat the offer of a structured meeting to try to better understand [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s position, and explore how a viable supplier relationship might be re-established and sustained, and I would hope that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] feels in a position to accept the offer.

SHONA ROBISON

Decontamination Services

Central Decontamination Unit
Mile-End Avenue
ABERDEEN
AB25 2ZN

NHS Grampian

Mr [redacted]
Managing Director
Medical Devices UK Ltd

Date 8th August 2018
Reference: MDUK/LW31082018
Enquiries to [redacted]
Extension [redacted]
Direct Line 01224 [redacted]
Email [redacted]@nhs.net

Dear [redacted]

Medical Device UK Contract – Wassenburg Servicing & Testing

Thank for your response to my letter of 8th August, dated 16th August 2018.

I note that you have not addressed my concerns as detailed below:

Manufacturer Training

You will be aware that the national NHS guidance (SHTM 2030) requires that maintenance persons for washer disinfectors should have "documentary evidence to demonstrate competence in the maintenance of one or more types of washer disinfector".

You have raised this requirement on several occasions related to previous changes in our service arrangements. In a note to your political representative earlier this year, you highlight the requirement for a "manufacturer's certificate of competence" for people working on medical disinfection equipment. This rightly caused us to reassure ourselves that manufacturer training was completed and certified before making any changes.

Given the emphasis you have previously placed on this, we are surprised that you are not able or willing to provide similar documentary evidence of competence for your own staff, despite repeated request for this.

This specific documentation is not required for the appointment to a national framework agreement but rather is a requirement to be fulfilled locally, dependent on the specific scope of work.

We are responsible for assuring that third party engineers working on our equipment are competent and it is essential you facilitate this in respect of your staff.

Provision of Spare Parts/Service Kits

You will also be aware that the fitting of manufacturer-approved parts which directly impact on the function of a medical device is essential to maintain the manufacturer's assurance of equipment performance and durability as well as the machine warranty.

You again raised this requirement previously related to other changes in our service arrangements. In a note to your political representative earlier this year, you highlight the requirement for "certification of all components". As with your comments on manufacturer training, this caused us to reassure ourselves that only manufacturer-approved parts were being fitted to our equipment where these directly impact on the effective functioning of the equipment.

Your contract with us is inclusive of parts and spares for the quarterly service visits. You have advised us that you source parts from the same supply chain as our equipment

manufacturer. This in itself does not mean that the parts have been tested and approved by Wassenburg.

We understand that Wassenburg will not sell spare parts to your company and we need assurance from Wassenburg that your alternative sourcing arrangements meet their approval criteria. This is essential so that we can assure ourselves that we are providing an effective decontamination service.

Service Schedules

With regard to the manufacturer's recommended half-yearly service, we need documentary assurance that this has been carried out to the manufacturer's specification. You have advised that this has been recorded and can be provided.

Following the failure of an equipment component, we have been made aware that our equipment manufacturer's recommended maintenance includes ongoing 2 yearly and 5 yearly service intervals.

We acknowledge that is not part of the service and testing scope that you priced. However, as our current third party engineering contractor for Wassenburg equipment, we feel this and the need to replace equipment-critical parts should have been raised with us.

The requirements listed below compromise the effective delivery of the contracted service with Medical Devices UK and constitute a material breach of the Framework Agreement.

1. Provision of documentary evidence of staff competence to service Wassenburg washer disinfectors.
2. Provision of documentary evidence that the parts fitted to our Wassenburg washer disinfectors that have a direct impact on the function of the equipment are approved by the manufacturer.
3. Provision of documentation that assures that servicing and testing have been completed as specified by the manufacturer.

Accordingly, we formally request that you satisfy the above requirements to our satisfaction within the next 30 days.

Finally, we are very disappointed that you relate our request for assurance to a concern raised by you in September 2017. We have assured you on several occasions that we appreciate the proactive raising of concerns.

We have reviewed the specific concern raised on several occasions involving Health Facilities Scotland, the equipment manufacturer (Wassenburg) and the chemical supplier (Dr Weigert). As an additional precaution, we also reported your persistent concern IRIC recently who have investigated to their and our satisfaction.

Yours sincerely

[redacted]

Decontamination Unit Manager

cc [redacted], Authorised Person (Decontamination)
[redacted] Decontamination Lead
Gavin Payne, Deputy Director Facilities & Estates
[redacted] Commodity Manager, National Procurement

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Please see letter that just gone out this afternoon.

Regards

Paul

Paul Allen
Director of Facilities & Estates

paul.allen@nhs.net
T: 01224 559533

NHS Grampian
Facilities & Estates
Foresterhill Health Campus
Aberdeen
AB25 2ZN

From: ALLEN, Paul (NHS GRAMPIAN)
Sent: 31 August 2018 09:14
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

Will do

Regards

Paul

Paul Allen
Director of Facilities & Estates

paul.allen@nhs.net
T: 01224 559533

NHS Grampian
Facilities & Estates Building
Foresterhill Health Campus
Aberdeen
AB25 2ZN

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 31 August 2018 08:57
To: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

Thanks Paul. Yes, appreciated if you could keep me up to speed with what happens.

Kind regards

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

From: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Sent: 31 August 2018 08:55
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION

(S38(1)(B)]) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@gov.scot>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

There has been another development involving the management of the contract Medical Devices UK where they are not meeting the obligations of the contract. We will issue the letter to [REDACTED – PERSONAL INFORMATION (S38(1)(B)] of Medical Devices UK today to give the 30 days' notice to rectify a number of issues which will no doubt trigger some complaint via our politicians when they receive the letter.

I will keep you appraised and send you a copy of the letter.

Regards

Paul

Paul Allen
Director of Facilities & Estates

paul.allen@nhs.net
T: 01224 559533

NHS Grampian
Facilities & Estates Building
Foresterhill Health Campus
Aberdeen
AB25 2ZN

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 31 August 2018 08:49
To: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

Sorry for the delay in replying, but thanks very much for this Paul.

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

From: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Sent: 31 July 2018 12:49
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)]) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@gov.scot>; GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN) <nhsg.grampianchiefexecutive@nhs.net>
Cc: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)]) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@gov.scot>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

With reference to your note of 26th July, we are concerned that allegations continue to be made by our supplier [REDACTED – PERSONAL INFORMATION (S38(1)(B)] of Medical Devices UK, despite these being addressed previously.

That said, we take all safety concerns very seriously and have revisited this topic accordingly. This specific issue is related to our use of the disinfectant *neodisher endo® SEPT PAC* versus *neodisher® Septo PAC*, both produced by the manufacturer Dr Weigert GmbH & Co. KG. Dr Weigert is an established supplier of specialist detergents and disinfectants to Wassenburg, one of our key decontamination equipment suppliers. Dr Weigert also provides their products through wholesalers to the NHS.

Dr Weigert formally advised customers of a brand name change on 15th March 2013 (*neodisher® Septo PAC* now available as *neodisher endo® SEPT PAC*), clearly indicating that the chemical had not changed and only the volume provided in each canister was different. This change was to improve user safety (see the attached customer information).

The original product (*neodisher® Septo PAC*) had been 'type tested' by our equipment supplier (Wassenburg) and therefore the identical chemical product, used in exactly the same way, has been accepted as being equally effective. Dr Weigert's advice note of 15th March 2013 also says "this customer information can be added to validation documents, if required" which is consistent with no additional type-testing or validation being needed.

Updated product information was provided for *neodisher endo® SEPT PAC* in November 2016 which explicitly says the product is suitable for the decontamination equipment we use in NHS Grampian (Wassenburg WD 440 endoscope washers). This information is also attached for your information.

[REDACTED – PERSONAL INFORMATION (S38(1)(B)] appears to be suggesting that the use of *neodisher endo® SEPT PAC* is an 'incident' with potential patient-safety, which is clearly not the case. We have the disinfectant manufacturer's written assurance that this is the same chemical, only in a lesser-filled canister. We note [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s comments, however, given the assurances we have had from the equipment manufacturer, the chemical supplier and our independent Authorising Engineer from Health Facilities Scotland, we are confident that this does not indicate any risk to patients at all. We are therefore unsure of [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s reasoning behind this allegation.

[REDACTED – PERSONAL INFORMATION (S38(1)(B)] also comments that Mr Payne (Deputy Director for Facilities and Estates) was not aware of the alleged 'incident' or [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s concerns when they met in early June. After enquiring further, it was clear that [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s original comments, made around October 2017 on this issue, had been sent to a number of local and national-level NHS managers and specialists in decontamination. There was consensus and confidence at that time that there was no 'incident' or patient risk and these suggestions were accordingly not escalated further.

As an additional level of assurance, our equipment and decontamination processes are subject to regular efficacy testing and have passed their annual tests using the re-branded chemical. These tests are carried out by Health Facilities Scotland to provide a level of independent assurance.

We do note the e-mail from Dr Weigert ([REDACTED – PERSONAL INFORMATION (S38(1)(B)], Business Development Manager) to [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and believe this needs clarification. Accordingly, we have made direct enquiries to Dr Weigert and Wassenburg and will raise a national-level incident report (IRIC) to formally address the need for clarification and provide additional assurance to ourselves other NHS Scotland Boards.

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s primary reason for meeting with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] in June was that the relationship with Medical Devices UK has

become increasingly unsatisfactory, apparently linked to NHS Grampian's reduced spend with that supplier and our attempts to address a number of contract performance issues. As you are aware, [REDACTED – PERSONAL INFORMATION (S38(1)(B)] has made many and varied allegations though several routes to NHS Grampian, all of which we believe have been addressed thoroughly and satisfactorily.

We will continue to respond positively to all safety concerns that are raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)], in parallel with managing the contract performance issues that we have raised with him and his company. We will continue to do this in collaboration with NHS National Procurement who will take a more national view of the performance of MD UK.

Thanks

Paul

Paul Allen
Director of Facilities & Estates

paul.allen@nhs.net
T: 01224 559533

NHS Grampian
Facilities & Estates
Foresterhill Health Campus
Aberdeen
AB25 2ZN

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 26 July 2018 09:41
To: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>; GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN) <nhsg.grampianchiefexecutive@nhs.net>
Cc: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] (SCOTTISH GOVERNMENT HEALTH & SOCIAL CARE DIRECTORATE) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk>
Subject: FW: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

Hi Paul and [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

You will recall our previous correspondence about Medical Devices UK. The Cabinet Secretary has been contacted again about the issue (please see attached), and I wondered if you might be able to fill me in on the latest, in order that the Cabinet Secretary can reply?

Possible you could come back to me by next Wednesday?

Many thanks

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

From: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Sent: 18 May 2018 08:00
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)]) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@gov.scot>
Cc: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN) <nhsg.grampianchiefexecutive@nhs.net>; [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION

(S38(1)(B)]) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@gov.scot>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Please see the following additional clarification to the points raised.

Regarding the suggested inconsistency between prior communications, we report and review all adverse events. Where required by our standards, we also conduct a formal investigation. I am aware of the previous accusations of 'safety breaches' by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and we have been clear throughout that all potential patent-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact which we believe was suggested by [REDACTED – PERSONAL INFORMATION (S38(1)(B)].

The adverse events [REDACTED – PERSONAL INFORMATION (S38(1)(B)] refers to were reported to Incident Reporting and Investigation Centre (IRIC) (as they always are) and as appropriate these were investigated by a multi-disciplinary team including HFS specialist input. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. I am not sure what issue [REDACTED – PERSONAL INFORMATION (S38(1)(B)] believes has not been rectified, as he has raised numerous concerns in his various communications.

As you know, we have very recently (on Tuesday 15th May) had the decontamination 'expert' team from Health Facilities Scotland (HFS) review the management of the issues raised to by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and also our current service arrangements. This was primarily in response to [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s numerous and continuing wide-ranging challenges. We await the written report from HFS but the verbal feedback from them was that that they support the previous investigation outcomes which indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] was very low indeed.

With regard to two different systems being in place. All areas of NHS Grampian operate to the same national NHS Decontamination Standards and the NHSG governance structure covers all locations. The operational arrangements to deliver the service will differ between locations for good reason. For example, in Aberdeen we have an established Decontamination Service, separate to the clinical teams. This is an appropriate arrangement given of the scale of the activities concentrated around Aberdeen as a city. By contrast, at Dr Gray's Hospital in Elgin where the level of activity is much lower, the decontamination team is integrated within the clinical team.

We use specialist decontamination equipment contractors, including Medical Devices UK, where we don't have the in-house competence and/or where this is best value for NHS Grampian. We have an ongoing contract with Medical Devices UK for the periodic validation of our automatic endoscope re-processors in Aberdeen and there is no plan to change this. There is a separate ongoing contract for the same type of work in Dr Gray's Hospital in Elgin. We have maintenance contracts with other specialist companies for different types of equipment, commonly with the original equipment manufacturer or supplier.

We previously had a contract with Medical Devices UK for the maintenance and testing of our endoscope storage cabinets in Aberdeen. We have made a decision to transition this work in-house in a controlled way. This provides both a technically competent solution and much better value for NHSG. This type of work is still out-sourced to Medical Devices UK for Dr Gray's Hospital in Elgin.

As with [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s suggestions on patent safety breaches, the team from HFS reviewed our current service arrangements on 15th May. HFS have verbally indicated their satisfaction with what we are doing and we expect this to be confirmed in the written report when it is issued.

Our relationship with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] and therefore Medical Devices UK is becoming increasingly difficult. As you are aware, we did offer to meet him personally on Monday 14th May together with our local service manager to see how best to move forward. The local management team were understandably cautious, given the wide range of issued raised and that these have been escalated quickly through different routes. However, [REDACTED – PERSONAL INFORMATION (S38(1)(B)] later declined the offer, saying he did not want to meet without a formal agenda and representation. In the meantime, staff from Medical Devices UK have been on site this week doing their normal work.

We plan to repeat the offer of a structured meeting to try to better understand his core concerns and how a viable supplier relationship might be re-established and sustained.

Finally, it is very unfortunate that these are being raised in this way as part of our contractual service relationship, which instead should have been highlighted through the course of any service visits to our sites. What is interesting here, is that these issue are now only being raised following the changes to our revised service model requirements with Medical Devices UK and elements which were previously serviced by Medical Devices UK are now being delivered in-house.

Regards

Paul

Paul Allen
General Manager
Facilities & Estates

paul.allen@nhs.net
T: 01224 559533

NHS Grampian
Facilities & Estates Building
Foresterhill Health Campus
Aberdeen
AB25 2ZN

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 17 May 2018 11:03
To: ALLEN, Paul (NHS GRAMPIAN) <paul.allen@nhs.net>
Cc: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN) <nhsg.grampianchiefexecutive@nhs.net>; [REDACTED – PERSONAL INFORMATION (S38(1)(B)] (SCOTTISH GOVERNMENT HEALTH & SOCIAL CARE DIRECTORATE) <[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk>
Subject: RE: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

Hi Paul

Sorry to bother you about this one again. The company has now raised this issue with the Deputy First Minister, who has written to the Cabinet Secretary about it (please see attached).

I would be grateful if you could give me any comments on this further letter that could help us to reply? The point about a contradiction refers to the statements made in the two attached letters that we've previously received from the Health Board, the first stating that no incidents have been

reported, and the second stating that any potential adverse events have been reported? Could you possibly clarify that for me?

Also, I've had a phone call from the Cabinet Secretary's office. She has concerns that there may potentially be two different systems being put in place across two sites here, with Medical Devices UK's services being used in Dr Grey's Hospital, but not at Aberdeen Royal Infirmary. Possible you could clarify that too?

Many thanks

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

From: ALLEN, Paul (NHS GRAMPIAN) [mailto:paul.allen@nhs.net]
Sent: 15 May 2018 08:42
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)])
Subject: Re: FOR ACTION: Alex Neil - decontamination equipment (260218-CAB-MW-01.3-lb)

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Following our telephone conversation on Friday, unfortunately the planned meeting with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] of Medical Devices Scotland did not go ahead yesterday. We will of course still aim to meet with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] but unclear of when at this stage.

Regards

Paul Allen

NHS Grampian - Corporate Administration Services
Address: Room F113, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE
Direct Dial: (01224 5) 58642
Email: nhsg.grampianchiefexecutive@nhs.net

NHS Grampian - Caring . Listening . Improving

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 10 May 2018 13:18
To: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN)
Subject: FW: Alex Neil - decontamination equipment (260218-CAB-MW-01.2a-lb)

Hi [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Thanks very much for this, and sorry for coming back on it again.

I had a phone call today from an Amy [REDACTED – PERSONAL INFORMATION (S38(1)(B)], who claimed to be the person that Mr Neill has written on behalf. She also had another person on the phone with her who she said was a 'Director' but I didn't catch his name. I didn't discuss anything with them in detail, but they were asking for a meeting with the Cabinet Secretary to discuss their concerns. They also mentioned that '5,000 patients' might be affected by the issue they've raised and – as you mentioned the other week – said they are taking legal action.

I said that if they wanted to meet with the Cabinet Secretary they should write to us to request a meeting, and we'd then consider the request. However, in the meantime, I wonder can you give me any more background on this? I'm wondering who exactly these people are, and what exactly their legal action is? If I remember correctly, do they represent a company that previously carried out decontamination services?

I'm not planning to discuss anything with them in detail should they contact me again, but it's just that it would be useful to know what exactly I am dealing with, and it will also help me advise the Cabinet Secretary accordingly, if they do write in to request a meeting with her.

Many thanks

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

[REDACTED – PERSONAL INFORMATION (S38(1)(B)] Bishop
Scottish Government | Directorate for Health Finance and Infrastructure

Basement Rear, St Andrew's House, Regent Road, Edinburgh, EH1 3DG
Tel: 0131 244 1816

From: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN)
[mailto:nhsg.grampianchiefexecutive@nhs.net]
Sent: 03 April 2018 16:56
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)])
Subject: RE: Alex Neil - decontamination equipment (260218-CAB-MW-01.2a-lb)

Good afternoon [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Apologies for the delay in replying – our information governance colleagues have now confirmed they have no issue with the content of our reply, therefore please now find this attached.

Kind Regards,

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]
PA to the Chief Executive, NHS Grampian
(Please note my personal email account is no longer in use – use office email)

NHS Grampian - Corporate Administration Services
Address: Room F113, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE
Direct Dial: (01224 5) 58642
Email: nhsg.grampianchiefexecutive@nhs.net

NHS Grampian - Caring . Listening . Improving

From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 03 April 2018 09:02
To: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN)
Subject: RE: Alex Neil - decontamination equipment (260218-CAB-MW-01.2-lb)

Hi [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Thank you for this. I will need to put some form of reply out to Mr Neil today, so would you be happy with the Cabinet Secretary replying along the following lines:

"I am grateful for your further letter in connection with decontamination services within NHS Grampian. As I stated in my previous letter, The Health Board has confirmed that its decontamination service presently abides by the arrangements put in place by NHS National Procurement with regard to the NHS Scotland National Framework Contract for Decontamination Services. However, I do note your constituent's continued concerns, and I have therefore asked Scottish Government officials to liaise further with the Health Board on the matter, and I will provide you with an update as soon as I am able."

Many thanks, and hope you enjoyed the holiday weekend.

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

From: GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN)
[mailto:nhsg.grampianchiefexecutive@nhs.net]
Sent: 26 March 2018 15:53
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)] ([REDACTED – PERSONAL INFORMATION (S38(1)(B)])
Subject: RE: Alex Neil - decontamination equipment (260218-CAB-MW-01.2-lb)

Good afternoon [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Following my phone call of this afternoon, I write to acknowledge the further correspondence received as below. This is being taken forward and the response will be shared once this is available.

As discussed, due to the specific nature of the further enquiries and the direct communication we have received from solicitors instructed by the correspondent, our response to the latest queries may require advice from Information Governance and Central Legal Office colleagues. This will likely delay our response beyond your requested timeframe, however we will remain in touch to provide updates as the response progresses.

Kind Regards,

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]
PA to the Chief Executive, NHS Grampian
(Please note my personal email account is no longer in use – use office email)

NHS Grampian - Corporate Administration Services
Address: Room F113, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE
Direct Dial: (01224 5) 58642
Email: nhsg.grampianchiefexecutive@nhs.net

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From: [REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk [mailto:[REDACTED – PERSONAL INFORMATION (S38(1)(B)]@scotland.gsi.gov.uk]
Sent: 26 March 2018 13:58
To: [REDACTED – PERSONAL INFORMATION (S38(1)(B)], [REDACTED – PERSONAL INFORMATION (S38(1)(B)] (NHS GRAMPIAN); GRAMPIANCHIEFEXECUTIVE, nhsg (NHS GRAMPIAN)
Subject: Alex Neil - decontamination equipment

Hi [REDACTED – PERSONAL INFORMATION (S38(1)(B)]

Last month you were kind enough to help me with some correspondence we had from Alex Neil about decontamination. Mr Neil's constituent has come back with further questions in light of the reply we gave. Would you mind looking over this and giving me some further comment that might help us to reply again? I also attach your recent letter to us, and the reply that we put out to Mr Neil after we received your letter.

If you were able to get back to me by this Thursday, it would be much appreciated.

Kind regards

[REDACTED – PERSONAL INFORMATION (S38(1)(B)]

[REDACTED – PERSONAL INFORMATION (S38(1)(B)] Bishop
Scottish Government | Directorate for Health Finance and Infrastructure

Basement Rear, St Andrew's House, Regent Road, Edinburgh, EH1 3DG
Tel: 0131 244 1816

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Dh'fhaodadh gum bi teachdaireachd sam bith bho Riaghaltas na h-Alba air a chlàradh neo air a sgrùdadh airson dearbhadh gu bheil an siostam ag obair gu h-èifeachdach neo airson adhbhar laghail eile. Dh'fhaodadh nach eil beachdan anns a' phost-d seo co-ionann ri beachdan Riaghaltas na h-Alba.
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PS MINUTE FOR CASE 2019/00010663

Medical Devices UK Limited (through political representatives) have been in touch with us since early 2018, regarding their ongoing dispute with NHS Grampian.

See attached the previous correspondence.

NHS Grampian have said that they have an ongoing but difficult working relationship with Medical Devices UK Ltd. Central Legal Office (CLO) are currently supporting NHSG with the early termination of a contractual relationship with MDUK relating to the maintenance of endoscope washers at Aberdeen Royal Infirmary. This matter is the subject of ongoing negotiations between CLO and MDUK's solicitors.

MDUK continue to provide testing and servicing to other types of equipment in NHSG, where adequate assurance has been provided.

As there is active legal work relating to this contract, I do not consider we should comment.

Correspondence with Alex Neil, February 2018

From: Neil A (Alex), MSP [mailto:Alex.Neil.msp@parliament.scot]
Sent: 21 February 2018 10:13
To: Cabinet Secretary for Health and Sport
Subject: NHSS National Framework Contract for Decontamination Devices-Grampian NHS
Importance: High

Dear Shona

I have been asked by one of my constituents, who wishes to remain anonymous, to bring the following situation to your attention, as it presents a potential risk to patient safety in NHS Grampian

Despite there being an NHSS National Framework Contract for Decontamination Devices it appears that the Head of Decontamination within NHS Grampian has stopped using these approved contractors for certain devices.

For example a company which isn't a Framework contractor has been brought in provide endoscope storage cabinets and apparently safety requirements are being flouted.

For example: the new company apparently does not possess an appropriate certification; safety features are being overridden; there is a question mark over whether it has the necessary indemnity insurance for the work it is doing; as well as a question mark over whether the service components are being changed every 6 months as they are required to be to protect patient safety/desiccant filter issues.

I am informed that there have been 4 safety breaches in Aberdeen Royal Infirmary Endoscopy Department since this company took over the contract, including a failed BSI audit.

Clearly if these allegations are true then urgent action is needed to investigate why a non-Framework contractor is being used and what action now needs to be taken to ensure that patient safety is not being compromised.

Meantime I would appreciate it if you could please advise your response

In appreciation

Yours sincerely

Alex Neil MSP

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0006670
March 2018

Thank you for your email of 21 February concerning decontamination services at NHS Grampian.

The Health Board has confirmed that its decontamination service abides by the arrangements put in place by NHS National Procurement with regard to the NHS Scotland National Framework Contract for Decontamination Services. I understand that, at present, the Health Board does not have a service contract in place for the testing and validation of endoscopy service cabinets with a framework contractor. Instead, arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.

Whilst the transition is underway, the service has engaged appropriate short-term training and support from a third party company who have the necessary qualifications and expertise to provide this. The Health Board confirms that this has been done in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the BSI Audit, NHS Grampian confirms that its decontamination service holds certification to BS EN ISO 13485 for all areas, and has never failed an audit. The most recent audit took place in February, with the outcome being a recommendation for the continuation of certification.

Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department, the Health Board advises that no such incidents have been reported.

I hope this is helpful.

SHONA ROBISON

Correspondence with Alex Neil, March 2018

Dear Shona
Many thanks for your reply to me dated 21st March regarding decontamination services in NHS Grampian
I have shared your response with my constituent, who wishes to remain anonymous
Please find attached his comments
I would appreciate you giving detailed consideration to each of the points and advice accordingly
Meantime I look forward to hearing from you
Yours sincerely
Alex Neil MSP
****
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Hi Alex,
Thank you for forwarding over the response from Shona Robinson.
I would like to make some comments in response to the letter received.
Paragraph 1
Arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.
All trusts agreed to sign up to a national contract to achieve best value from suppliers awarded national contracts,
All suppliers where asked to fix pricing throughout the framework period to enable the trust to budget.
This framework has now been extended for 25 months to allow national procurement to evaluate cost savings and publish a new framework agreement; suppliers again being ask to fix prices this would be a price fix for 5 years in total.
When the hospital wants to transition to in-house for best value this can only be achieved when the persons carrying out the work have the correct skill set qualifications and are changing out the stipulated components at each service interval. Otherwise the risk to patient safety is being compromised by cost for which budgets had been set aside, the criteria tendered for on the national

contract from the OJEU is not being carried out in accordance with the minimum requirements and to the standard BS EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.

Paragraph 2

Whilst the transition is underway, the service has engaged appropriate short - term training and support from a third party company who have the necessary qualifications and expertise to provide this. The health board confirm that this has been done in full compliance with the requirements of NHS Scotland framework contract, as confirmed with the relevant commodity manager at NHS procurement.

How long will the transition period be as the machines are still in use without a proper validation being performed?

The third party company who is providing the training to in-house staff has no manufacturer equipment experience, not approved by NHS framework or the OJEU for maintenance & testing of any Medical Device, it has never had to produce public liabilities insurance to the sum of £10,000,000 or never met the minimum requirements of the OJEU for quality management system ISO 9001: 2015 this is costs that all small companies have to endure to set up these systems to meet the basic requirement to apply for the national contracts.

Have we ignored the minimum requirements and risked patient safety?

What is the best value of using a non-approved contractor who has none of the above?

While we accept it is NHS Grampians decision to whom they allow to work on there equipment I must call to action the rational behind this decision on allowing an unqualified company to train unqualified personnel with no electrical, mechanical or electronic background to service and test medical equipment for use in patients.

NHS has a policy of any person working on equipment must be employed by estates department with a minimum 5 years electrical, mechanical trade experience before you can apply for a job as a band 5 test person.

The individuals being trained to carryout this work, have no such skill set and the jobs have never been advertised to persons with the relevant qualifications

Is this a question for HSE or Trade unions?

What is the value of the work being contracted out to the third party company should this have gone out to public tender?

This is an off contract spend surely this had to be carried out under a mini tender process at least.

Can the company providing the training assist with the health board providing a sample test report for the validation work undertaken that meets the requirements of the OJEU National procurements tender qualification envelope.

This should include but not limited to Manufacturers Certification of competency, Certification of all service components used on the service & revalidation of the equipment, Certification of all test equipment used to record the data along with current calibration certificates for all equipment.

Recorded in a document that is acceptable for the requirements.

Once this has been verified that all the requirements have been met then this could prove to be best value.

If all parameters are not met then we do not have a level playing field?

Are the national contracts worth the effort put in to become an approved

supplier?

Paragraph 3

The most recent audit took place in February, with the outcome being a recommendation for the continuation of the certification.

The audit was carried out for a second time within the endoscopy unit due to the failings identified within the endoscopy department in the previous audit.

The unit had to report an incident to MHRA for the use of non-validated chemicals being inserted into machines to perform high-level disinfection processes on endoscopes for use in patients in June 2017 and a subsequent IRIC investigation took place and found the unit at fault for all matters concerned.

After this investigation was completed the unit then proceeded to do this 2 further times but choose to ignore the incidents.

The head of decontamination, the decontamination manager, quality & safety manager, Health facilities Scotland authorising engineer where all informed but all choose not to respond.

Email chain can be provided.

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0009997
April 2018

I am grateful for your further letter in connection with decontamination services within NHS Grampian.

Managers of the decontamination services at NHS Grampian are fully aware of the technical requirements of the work in question, and have given reassurances that they will not compromise on those. The Health Board is investing in the skill-set of in-house staff and is confident that staff will achieve the required certification as planned.

As I stated in my previous letter, NHS Grampian has contracted a suitably qualified and experienced third-party to provide interim support, where required, during the transition period. The Health Board confirms that these arrangements are in full compliance with the NHS Scotland framework, as agreed by the relevant commodity manager at NHS National Procurement.

Finally, in relation to the BSI audit, the Health Board again states that this was carried out in February 2018 and continuing certification has been confirmed. The Health Board has also provided reassurance that it routinely reports all potentially adverse incidents to the Incident Reporting and Investigating Centre as standard, and these are further reported to the Medicines and Healthcare Products Regulatory Agency where appropriate. The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated, and concluded satisfactorily.

I hope this is helpful.

SHONA ROBISON

Correspondence with John Swinney, May 2018

From: Swinney J (John), MSP [mailto:John.Swinney.msp@parliament.scot]
Sent: 17 May 2018 10:04
To: Deputy First Minister and Cabinet Secretary for Education and Skills
Subject: Medical Devices U.K.
Could you please pass this to Ms Robisons's Ministerial Office.
Thanks.
J
Dear Shona,
Medical Devices UK
I refer to our conversation on Tuesday regarding the concerns of Medical Devices U.K., a company based in my Constituency, regarding their contractual arrangements with NHS Grampian.
Medical Devices U.K. provides an independent testing and validation service for decontamination facilities of a medical device. The scheduled testing programme is to assess that the equipment is operating to the defined parameters of the commissioning data recorded at the time of the installation process. The company provides these services at Aberdeen Royal Infirmary and at other NHS sites through a framework contract that has brought savings to the NHS.
In both September 2017 and February 2018 the company identified potential patient safety risks due to changes to the processes for cleaning equipment to ensure effective decontamination. I understand that the event in September 2017 was rectified but the event in February 2018 May not have been.
This issue has been raised by the company through Alex Neil MSP with whom you corresponded on 21 March and 24 April. The company point out that in your letter of 21 March, you state :
"Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department,the Health Board advises that no such incidents have been reported."
In your letter of 24 April, the company point out that you state :
"The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated and concluded satisfactorily."
The company make the point that there appears to be a contradiction between these two statements. In addition, they make the point that they do not believe the statement quoted from your letter of 24 April to be accurate as they believe not all of the incidents have been rectified.
The company have raised these concerns - as they are contractually bound to do - and now find that they are no longer to be used by Aberdeen Royal Infirmary to provide these validation services.
I would be grateful if these concerns could be looked into with vigour to provide clarity for my constituents.
I look forward to hearing from you.
Yours sincerely,
John
John Swinney
MSP for Perthshire North

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr John Swinney MSP
The Scottish Parliament
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Our ref: 2018/0016281
13 June 2018

Dear John,

Thank you for your email of 17 May concerning Medical Devices UK and decontamination services within NHS Grampian.

As you are aware, I have previously corresponded with Alex Neil on this issue and, in light of the concerns raised by Mr Neil, the Health Board confirmed that it is making arrangements for the in-house provision of decontamination services and is doing so in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the suggested inconsistency concerning potential safety breaches or adverse events, the Health Board confirms that it reports and reviews all adverse events and, where required, also conducts a formal investigation. The Health Board is aware of Mr Donnelly's concerns, but has been clear throughout that all potential patient-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact of a type that the Health Board understands was suggested by Mr Donnelly.

The adverse events that Mr Donnelly has referred to were reported to Incident Reporting and Investigation Centre (as per standard procedure) and, as appropriate, these were investigated by a multi-disciplinary team that included input from Health Facilities Scotland. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. With respect to issues that Mr Donnelly believes have not been rectified, the Health Board is unclear as to what is being referred to.

On 15 May the Health Board had a decontamination expert team from Health Facilities Scotland review the management of the issues raised by Mr Donnelly and also our current service arrangements. This was primarily in response to Mr Donnelly's continuing challenges. Whilst the Health Board awaits the written report from Health Facilities Scotland, verbal feedback was that that they support the previous investigation outcomes which indicates that the chance of any actual patient harm associated with the issues raised by Mr Donnelly was very low indeed.

I am aware that the Health Board offered to meet Mr Donnelly on 14 May in order to attempt to move forward from the present situation, though I understand that Mr Donnelly subsequently declined the offer. The Health Board confirms that it plans to repeat the offer of a structured meeting to try to better understand Mr Donnelly's position, and explore how a viable supplier relationship might be re-established and sustained, and I would hope that Mr Donnelly feels in a position to accept the offer.

SHONA ROBISON

Letter from John Swinney – 13 July 2018

Dear Cabinet Secretary,

Re: Medical Devices UK

I wrote to Shona Robison on 17th May 2018 regarding the concerns of my constituents, Amy and Jason Donnelly, who are Directors of Medical Devices UK.

Shona Robison replied to me on 13th June 2018 and I have discussed this matter with my constituents who remain concerned that the contents of the reply that came from the Health Secretary.

In the reply of 13th June, Shona Robison stated that 'all potential patient safety concerns have been reviewed satisfactorily'. My constituent disputes the veracity of that statement as the process that was applied was a non validated process so there is no way in which the concerns could have been addressed satisfactorily.

When my constituents discussed the incident that took place in September 2017, in NHS Grampian, with Mr Payne, he was unaware there was an incident which had caused difficulty and concern in September 2017.

My constituent is concerned that NHS Grampian is not properly investigating this issue. I enclose two e mails, one from the manufacturer of the equipment which indicates that a particular fluid that was used has not been tested by the manufacturer despite the fact that my constituent has been told that it has been approved by the manufacturer.

I cite these two examples to illustrate that my constituent really is dissatisfied that NHS Grampian is not properly and fully investigating this matter and providing quality information to the Scottish Government to address these concerns.

I would be grateful if you would look further into this matter and ensure that the concerns of my constituent are fully and properly addressed.

Yours sincerely,

John Swinney, MSP

Letter dictated by Mr Swinney and signed in his absence

Enc

Cabinet Secretary for Health and Sport
Jeane Freeman MSP

Scottish Government
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Mr John Swinney MSP
The Scottish Parliament
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Your ref: JS3471CS
Our ref: 2018/0024778
August 2018

Thank you for your letter of 13 July, on behalf of your constituents Amy and Jason Donnelly, concerning decontamination services at NHS Grampian.

The Health Board has confirmed to me that the specific issue raised by Mr and Mrs Donnelly relates, in this instance, to its use of the disinfectant *neodisher endo® SEPT PAC* versus *neodisher® Septo PAC*, both produced by the manufacturer Dr Weigert GmbH & Co. KG. Dr Weigert is an established supplier of specialist detergents and disinfectants to Wassenburg, one of NHS Grampian's key decontamination equipment suppliers. Dr Weigert also provides products through wholesalers to the NHS.

Dr Weigert formally advised customers of a brand name change on 15 March 2013, with *neodisher® Septo PAC* becoming *neodisher endo® SEPT PAC*. The Health Board confirms that, in doing so, the company clearly indicating that the chemical had not changed and only the volume provided in each canister was different. This change was to improve user safety.

The original product (*neodisher® Septo PAC*) had been 'type tested' by NHS Grampian's equipment supplier (Wassenburg) and therefore the identical chemical product, used in exactly the same way, has been accepted as being equally effective. Dr Weigert's advice note of 15 March 2013 also says "this customer

information can be added to validation documents, if required" which is consistent with no additional type-testing or validation being needed.

The Health Board further confirms that updated product information was provided for *neodisher endo® SEPT PAC* in November 2016, which explicitly says the product is suitable for the decontamination equipment used by NHS Grampian (Wassenburg WD 440 endoscope washers).

Given the above, NHS Grampian does not agree with Mr and Mrs Donnelly's assertion that the use of *neodisher endo® SEPT PAC* is an 'incident' with potential patient-safety, stating that it has the disinfectant manufacturer's written assurance that this is the same chemical, only in a lesser-filled canister. Although noting the Donnellys' comments, given the assurances the Health Board has had from the equipment manufacturer, the chemical supplier and its independent Authorising Engineer from Health Facilities Scotland, it is confident that this does not indicate any risk to patients.

With respect to the Donnellys' suggestion that Mr Payne (Deputy Director for Facilities and Estates) was not aware of the alleged incident or Mr Donnelly's concerns when they met in early June, the Health Board is aware that the Donnellys' original comments, made around October 2017 on this issue, had been sent to a number of local and national-level NHS managers and specialists in decontamination. There was consensus and confidence at that time that there was no incident or patient risk and these suggestions were accordingly not escalated further.

By way of an additional level of assurance, the Health Board also points out that equipment and decontamination processes are subject to regular efficacy testing, and it has passed annual tests using the re-branded chemical. These tests are carried out by Health Facilities Scotland to provide a level of independent assurance.

In light of the e-mail from Dr Weigert (Lee Readman, Business Development Manager) to Mr Donnelly, NHS Grampian has made direct enquiries to Dr Weigert and Wassenburg. Further, it will raise a national-level incident report (IRIC) to formally address the need for clarification and to obtain additional assurance both for itself and for other Health Boards.

I hope this helps to clarify the position.

JEANE FREEMAN