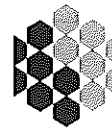


FROM THE MINISTER FOR HEALTH,
SOCIAL SERVICES AND PUBLIC SAFETY



Department of
**Health, Social Services
and Public Safety**

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Mrs Jo-Anne Dobson MLA
Room 307
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Ballymiscaw
Stormont
BT4 3XX

Our Ref: AQW 47507/11-15

Date: 5 November 2015

Dear

Jo-Anne

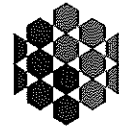
Further to my response dated 22 October 2015 to your Assembly Question requesting an update on the Aseptic Unit Audit conducted by a Regional Quality Assurance team at Craigavon Area Hospital in December 2014, I can confirm that work to address the findings relating to personnel, training, competency assessment and comprehensive contingency plans was completed in September 2015 rather than August 2015 as stated in my answer of 22 October 2015.

An updated response is attached to reflect the current position in respect of the Aseptic Unit Audit.

Please note that a copy of this letter will be forwarded to the Assembly Library.

Yours sincerely


SIMON HAMILTON MLA



Department of

**Health, Social Services
and Public Safety**

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Simon Hamilton MLA, Minister
Castle Buildings, Stormont Estate,
Belfast, BT4 3SQ

Mrs Jo-Anne Dobson MLA
Northern Ireland Assembly
Parliament Buildings
Stormont

5 NOVEMBER 2015

AQW 47507/11-15

Mrs Jo-Anne Dobson has asked:

To ask the Minister of Health, Social Services and Public Safety, for an update on the Aseptic Unit Audit which was conducted by a Regional Quality Assurance team at Craigavon Area Hospital in December 2014; and to further detail any non-compliance issues raised by this audit.

ANSWER

The RQA's December 2014 Audit made 9 findings. Of these one was classed as 'critical', one as 'major', and 7 as 'other minor'. The critical finding related to the facilities themselves which it judged did not meet EU requirements. A business case has been submitted to the Department and will be considered alongside other capital priorities. Other findings, related to aseptic processing; monitoring; documentation; product approval; materials, components & consumables and adherence to audit schedule, have been addressed. Work to address findings relating to personnel, training & competency assessment and the need for comprehensive contingency plans was completed in September 2015.

Simon Hamilton MLA