23 DEC 1980

DEPARTMENT OF HEALTH AND SOCIAL SECURITY
HANNIBAL HOUSE
ELEPHANT AND CASTLE LONDON SE1 6TE
TELEPHONE 01-703 6380 ext. GRO-C

Your reference
Our reference

22 December 1980

Dr R S Lane
Director
Blood Products Laboratory
Dagger Lane
Elstree
HERTFORDSHIRE WD3 6AX

Dear Richard

MEDICINES INSPECTORS' VISITS TO BPL

I have been sent the reports which Medicines Inspectors have made following visits to the Blood Products Laboratory on 26 November and 9 December.

I am obliged to present these reports to the Joint Management Committee, and anticipate that the Committee will wish to discuss them at its next meeting. I should not wish to do so, however, without letting you see them first, and I enclose copies.

In doing so I must emphasize, first, that the notes were originally intended only as a record for the file (they are marked accordingly) and therefore lack the polish customary in documents intended for a wider circulation; and, second, that the visits are not to be confused with formal inspections (I understand that the issues raised by Mr Flint came up only incidentally to the main purpose of his visit). Perhaps I should add, because the reports do not make the point, that in sending me the reports Medicines Division have told me that they are very conscious of the candid cooperation its inspectors have had from you.

One report mentions that Mr Leavens had not seen the main report of the inspectors following their formal inspection. I am rather surprised about this because (minus the inspectors recommendations, which are of course confidential) the report was sent to the staff side as well as you. Nevertheless, it seems appropriate for me to ask you to ensure that the contents of the report (not the recommendations) are communicated to staff who should know of them, and that the defects in procedures etc which have now been reported are similarly brought to their attention.

I assume that you will wish to report to the JMC on the steps you will, by the time of it meeting, have taken to remedy the shortcomings identified by the inspectors. I will see that the Secretary includes an appropriate item on the agenda.

In the context of these new reports I have asked colleagues in the Department to draft a job description for a factory manager. When I have this I will invite you to have a look at it, and I suggest we should then ask the JMC to agree to an appointment as soon as possible.

Yours sincerely

GRO-C

for J HARLEY

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NOTE FOR THE FILE

(1)

NOTE OF A VISIT TO THE BLOOD PRODUCTS LABORATORY, ELSTREE ON WEDNESDAY 26.11.80

Further to my meeting of 11 11 80 with Mr Dyke and Mr Bailey where insufficient information was available to me to make valid decisions on upgrading, Mr Leavens the BPL Technical Services Manager telephoned to say that the matter had been delegated to him and could he discuss the plans with me. I therefore arranged to visit Elstree as it was easier to make decisions on site.

At the start of the visit Mr Leavens introduced me to his new assistant Miss Valerie Plummer who has the title of Technical Services Supervisor and who joined the Laboratory on 1 August 1980. She has a City and Guilds degree in general science and was previously employed at the Institute of Dermatology. She has had no previous experience of sterilisation procedures but is now responsible for overseeing this activity at BPL.

Mr Leavens informed me that 3 point and 12 point temperature recorders have been purchased but used only on the ovens so far as there is no input point on the autoclaves; this matter was said to be under consideration by the engineers. It is clear therefore that the autoclaves have not yet been validated and Mr Leavens confirmed this.

BOWIE DICK TEST - to check that all air has been removed from steriliser

Bowie Dick tests are being done regularly on the porous load autoclaves and I was shown the test recordings which are being approved by Miss Plummer. On further questioning I do not think she was aware of the importance of different gradations of colour change being indicative of air pockets in the loads. All the charts I examined were satisfactory though.

Another worrying situation is that the sterilisation records are not seen by anyone outside the Technical Services Section and are therefore not seen by Dr Lane in releasing batches of product.

I was told that a Mr George Varley of Varley Engineering does three-monthly maintenance checks and as his next visit is in December he may fit the thermocouple ports in the autoclaves.

I was also informed that not all clothing is sterilised in the porous load autoclave as Tyvak shrinks and clothing of this material is sterilised in the downward displacement autoclave with a vacuum assist. Mr Leavens cannot therefore be certain that all the residual air is being removed from the machine.

I was also told that cleanroom clothing is still not being washed prior to sterilisation.

Mr Leavens is now using DRG 'window pack' sterilisation wrapping material in place of calico bags but only on his own initiative following my criticism of his sterilisation packs when I visited the Laboratory previously. He informed me that he was not aware that products for sterilisation had to be double wrapped as this information had not been passed to him by his senior officers. In fact he told me that he had <u>not seen the inspection report</u> (other than on Dr Lane's desk) and as far as he was aware neither had any other staff. He was therefore not aware of our requirements on any aspects; he was working in a void.

He then spoke to me about the Specialist Cleaning Service that was now in force. Since the cleaning contract started he told me that a female relief manager was put in but was so appalling that she was taken out again. A Pritchards office cleaner then replaced her as an interim measure prior to appointment of the present manager. Leavens said he was only partially satisfied with the cleaning service as the present manager is still learning the business.

Before looking at the plans again, I visited the wash-up and sterilisation areas to re-acquaint myself with the lay-out.

Dirty Reception Area

This is used for equipment, containers and components to be washed and sterilised.

It was also being used for storage of washed vials prior to sterilisation but they lost their batch numbers and some boxes were also unlidded.

Wash-up Area

This is entered from Dirty Reception and is used for:-

1. Washing used bottles prior to them being discarded.

2. Washing clean vials.

3. Washing equipment ie filters, Sharples centrifuges, production vessels, flasks etc.

4. Washing rubber closures.

The air filtration was said to be crude and there was no additional environmental protection.

There were also two metal hot air drying cabinets without filtered air protection and a cupboard holding washed coats.

The windows were open to the outside.

Staff were said by Mr Leavens not to know the GMP levels at which they had to work and were in need of strong direction from management.

A man brought in a bin of empty bottles for washing and also the dirty wrapping paper which should have been discarded in his own area. He was said to be aware of this rule but it was difficult to enforce. Miss Plummer made him remove the wrapping material from the area.

Aluminium trays for washed vials were stacked in the washing area but it is impossible for this type of tray to maintain sterility of the contents. The trays are therefore overwrapped with a nylon bag, which really acts as a dust cover and the open end is not sealed. These bags are re-used and stored in the washing area. Some of the vials sterilised in this way are freeze drying vials which are aseptically filled.

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Assembly Area

The wash up area leads into the assembly area where washed materials, equipment, Sharples centrifuges, filters, flasks etc are re-assembled and singly wrapped in DRG plastics/paper combination wrapping material.

Next is the autoclave room which opens from the clean side of the autoclaves into the sterile components store.

Component Washing Room No 227

On the opposite side of the corridor to the autoclaves is the Clean Preparation Area which is entered by an airlock.

The air filtration was said to be 95% efficient at 5u and 20 air changes per hour.

Mr Leavens is endeavouring to ensure that all vials and closures are washed here and packed for autoclaving but this is not always possible due to inadequate space.

PPF bottles are also washed here on the Miller-Hydro rotary washer and then sterilised through the ovens at the end of the area. The air flow was said to be from the sterilising ovens outwards to the corridor.

Plans for Upgrading

Dirty reception area - no change contemplated.

At present the air is filtered through a crude dust filter.

Said to get 20-25 air changes.

Washing Area - As in Dirty Reception Area.

Information given at meeting of 11 11 80 is incorrect as the air quality is not 95% at 5u. It passes through a bag filter with a 35% efficiency to the methylene blue test. Terminal filters are not to be fitted either.

I informed Mr Leavens that I could not advise on the plans for upgrading without firm details of exrating air systems, intentions for upgrading the air quality, possible use of portable LAF units over the washing machines, intentions for upgrading R 227, exact use to which the washing room is to be put, intentions for installing additional washing facilities when the coagulations Factors Unit is upgraded.

Mr Leavens said that he couldn't provide the answers at this stage as he was working in a total vacuum. He and others needed to be advised of overall policy and to this end they required a production manager and a quality controller. Mr Leavens told me that when he wished to discuss upgrading and quality assurance with senior staff the attitude was "it really doesn't matter".

I said that I would telephone him on Tuesday 2 December to ascertain whether he could get further information from Dr Lane to enable me to consider the plans more fully.

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NOTE FOR THE FILE

(2)

NOTE OF A VISIT TO BLOOD PRODUCTS LABORATORY, ELSTREE ON TUESDAY 9 DECEMBER 1980

Purpose of Visit:- For a final discussion and approval of plans for upgrading the wash-up and assembly areas previously reported following a similar visit on 26 November.

Present:

Dr R Lane	Director	
Mr L Vallet	Deputy Director	
Mr G M Bailey	Administrator	
Mr P Leavens	Technical Services	- during visit to wash up area only
Mr J K Ayling) Mr J Flint)	Medicines Inspectorate	

Discussion

Many general points were discussed as background information for Mr Ayling and will be reported separately by him.

The reason for this minute is to record that part of the discussion concerning matters discussed with Mr Leavens during the visit of 26 November and which needed to be confirmed by Dr Lane.

The matters that disturbed me were:-

1. Autoclaves still not validated even though 3-point and 12-point thermocouple sets had been purchased.

Dr Lane confirmed this.

2. Sterilisation charts and records not seen by Dr Lane in releasing batches of product.

Dr Lane confirmed this but explained that although procedures had been drafted they had not been fully implemented to our liking. He had so many other responsibilities and with shortages of key supporting staff he was unable to deal with everything.

3. I reminded him that Mr Leavens was providing an essential service in sterilising equipment and components and yet he had to rely on Miss Plummer to supervise the sterilisation operation. Miss Plummer was still under training and did not have any experience of sterilisation requirements prior to her appointment to BP Laboratory

4. I informed him that Mr Leavens was working in a "vacuum" - Leavens' own expression - and that senior management had failed to inform him of the Inspectorate requirements on sterilisation. Again Dr Lane blamed this on other priorities, especially considerations of upgrading and liaison with DHSS and also the lack of a factory manager.

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He said that he had informed Mr Leavens that if he ever had any problems then he should make them known to himself (Dr Lane). My reply was that Leavens only knew that he had a problem when he spoke to people like me and couldn't produce satisfactory answers to my questions.

It is essential that there should be a factory manager who is aware of policy and able to direct and manage the production departments as an entity and someone to whom staff like Mr Leavens could turn to with day to day problems.

5. I said that sterile room clothing was still not being washed prior to sterilisation and that this and other items were only singly wrapped for sterilisation.

I recognised that the problems of cleanroom clothing were associated with the provision of proper changing facilities and Dr Lane informed me that the latter prospect had been repeated by the Department and deleted from the current schemes for upgrading.

6. I had been told that the inspection report had not been seen by the staff even though it had been disclosed to the union and to Granada Television.

Dr Lane confirmed that the union had been given a copy and he knew that Granada TV had a copy together with a copy of our recommendations but that these latter copies had not been provided by BPL. He said that the heads of departments had discussed the report with him page by page but Mr Leavens was not a departmental head. I criticised the Departmental heads for not informing their staff of our requirements.

7. The key posts of engineer, factory manager (deputy to Dr Lane), microbiologist and quality controller had not been filled although I had this week seen a job description for the quality controller. I said that the factory manager was a key appointment that must be made and yet there had been no progress.

Dr Lane explained the problems with EP Division of DHSS in failing to appreciate the problem and offer adequate salaries; it was no use trying to relate these manufacturing posts to departmental grades that were irrelevant.

8. Although a cleaning contract had been negotiated and implemented there had been a number of changes in the management supervisor and the present manager did not have previous cleaning experience let alone specialist cleaning experience. This was not a specialist cleaning service and was not as effective as it should be.

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These were all points that came to light during a short discussion with the technical services manager and confirmed to day by Dr Lane.

It is apparent that the Laboratory is not being effectively managed and that there is little if any improvement since the initial inspections. This has not been helped by the considerations whether the Laboratory was to be handed over to industry and the delays inherent in such deliberations.

Improvements costing approximately £2 million pounds have been agreed and are being implemented but these are essentially to provide for extra production and will not provide a greater degree of safety as the basic deficiencies cannot be overcome in this building. Dr Lane said that he has initiated environmental monitoring studies that indicate changing microbial and particulate hazards on a cyclical basis. We did not see these results but will study them during the further in-depth inspection which we plan to carry out early in 1981.

From my discussions to date it is obvious that a hazard still exists at BPL and is likely to remain so unless priority is given to appointing the key staff referred to in the report and to the drawing up of plans to rebuild the Laboratory.

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NOTE FOR THE FILE

Looking for Copy

11 DEC 80

(3)

VISIT TO BLOOD PRODUCTS LABORATORY, ELSTREE.

Date : 9th December 1980

Inspectors : J Flint
K J Ayling

Personnel encountered :

Dr Lane	Director
Mr Bailey	Administrator
Mr Vallet	Deputy Director
Mr Wesley*	Head of Large Fractionation
Mr P Leavens	Technical Services Manager
Dr Singleton*	Blood Products Laboratory

* Met briefly only.

(Mr Pettet now occupies the position of Personal Assistant (Scientific) to Dr Lane.)

The visit was carried out in order to introduce Mr Ayling to Dr Lane and his staff and to discuss the plans for upgrading the preparation area. Dr Lane was made aware that inspection responsibility will be transferred from Mr Flint to Mr Ayling early in 1981.

Dr Lane reviewed the current situation at the Blood Products Laboratory.

The possibility of industrial participation has now ended.

The 'Stop Gap' proposals to upgrade the production facilities is to be implemented. This plan and other upgradings will cost £2M. This will only relieve present problems and does not provide extra capacity.

The hepatitis suite is to be upgraded by 28 March 1981 and a hepatitis R I A has been developed. Work on this suite is to start on January 5th.

A complete revamp of the coagulation factors area ("C.F.") is also scheduled, and this will provide some extra space. Plans for this are "under discussion" and a planning meeting had been held yesterday.

No extra finance is available for this unit. The time taken for this work is crucial since £50,000 of production would be lost per week of the shutdown.

The combined work to be carried out was referred to as "Ministerial Interim Programme plus Stop Gap".

I plans for the Preparation (Service) Area run by Mr Leavens do not include upgraded air filtration, but it is proposed to follow up the present proposed upgrading with an improved air input system i.e., as a Phase II.

It had been previously stressed that it was essential that the present plans for Mr Leavens area should not be altered further, or yet further delay could result.

The necessity of a proper administrative and financial structure for Elstree was stressed by Dr Lane.

A problem regarding this was said to be because the Treasury worked on "2 year cycles and this plan was for a 3 year cycle".

The £2M allocated for these holding operations does not include any financial contingency, but the Treasury were said to have agreed to fund inflation arising over the next 2 years.

Present output of Factors VIII and IX are £2.5M and £1M p.a. respectively. These are the replacement costs i.e., the cost to the NHS of buying commercial products.

The Granada Television programme regarding Blood Products Laboratories (i.e., Edinburgh and Elstree) is scheduled for Monday 15 December. Dr Lane has refused to be interviewed for this but the Minister has been interviewed.

Granada Television were said to have a copy of the Inspection Report by Messrs Flint, Purves and Holgate, including the recommendations made.

The A.S.T.M.S. was apparently supplied with a copy of the Inspection Report, but Dr Lane understood that this did not include the recommendations.

A Committee of MP's are visiting Elstree on Monday 15 December. This will also include ASTMS representatives, including Clive Jenkins. There is to be an Adjournment Debate in the House of Commons on 15 December on the Blood Transfusion Service.

Background matters regarding the last inspection and the Inspection Report was reviewed (see note by J. Flint for details).

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nts noted whilst in the Preparation (Service) Area for discussions regarding upgrading included the following :

1. Clothes are still not washed before autoclaving.
2. Staff had no hats on, yet . washed vials etc are handled in the open environment.
3. Certain plugs are sterilised by being placed loosely in bottles and then autoclaved with brown paper bags over the top.
4.
   a) Browne's tubes were left on top of an old oven in a very warm atmosphere. (These MUST be stored in a fridge or they give false results)
   b) Old cloth and debris were on top of the oven.
   c) Debris on old metal containers, etc were on the floor behind the bottle washer. A bolt from elsewhere had in fact congested onto the metal container.
5. Mr Leavens stated that this area was not under his control, and that Mr Vallet, the Deputy Director never asked any questions regarding his unit. Mr Leavens reports to Mr Vallet!
6. The entrance to the preparation areas was badly congested and it was difficult for operators to even wheel trucks through.. The fact that this must pose a fire hazard was pointed out to Mr Leavens.
7. Mr Leavens had previously intimated that he had never seen the Inspection Report.

Comment.

Such a unit as this undoubtedly requires a high standard of:

1. Management.
2. Facilities.
3. Control Systems.

The management of this Centre is very obviously not providing the proper control systems and the part of facility seen is badly congested and in parts poorly managed.

The absolute necessity for a proper management structure and control system must be of the highest priority. This would include the appointment of personnel

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at Factory Manager and Quality Controller level.

Only with the proper management can adequate systems of control be implemented. If this is not done, any investment in facilities and equipment will be nullified.

GRO-C

10 December 1980

K JOHN AYLING
Principal Inspector (Biologicals)
Medicines Inspectorate

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