Medicines Inspectorate Visit to B.P.L. including Technical Services section on 5th/6th March 81.

As a result of the above visit, the T.S.M. received a telephone call late on Friday evening from the Director, Dr. R.S. Lane, in which it was intimated that the operation of our moist steam steridisers was poorly managed, and that standards were unfortunate. He stated that he was considering the possibility of shutting the operation down until the steridisers had been validated. He requested information on the thermocouple entry compression joints which would enable us to start validation.

The T.S.M. advised that he hoped Vanley Engineering would deliver the equipment on Monday 9th March. Over the weekend, the TSM. followed this point through and it appears that the parts required will not be ready until the following Monday, 16th March when Mr Vanley will bring them to Elstree and commission the equipment.

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Despite difficult circumstances, Technical Services Section has made considerable progress towards improved management of the steriliser.

Routine daily/weekly operating checks and tests are now performed by the section and the engineers. (these were non existant at time of the 1979 inspection).

1	Recorder and temperature gauge agreement	DAILY
2	Check for cleanliness	"
3	Air leak test (porous load type only)	WEEKLY
4	Bowie Dick test " " " "	DAILY
5	Temperature Sensitive tape (all items)	"
6	Browne Control tubes " "	"
7	Door Seal check	WEEKLY
8	Door Safety devices	"
9	Steam traps	"
10	Clean chamber	"

Periodic tests are performed by the section and bacteriology depot.

11	Spore strip tests (microbiological control)		
12	Air filters	down displacement	MONTHLY
		porous load	3 MONTHLY
13	Thermocouple tests to come on line during MARCH 1981.		

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The tests and checks are supervised for T.C. by Mrs. V. Plummer. Dr Singleton is responsible for the growth and test results in microbiological test No 11, while tests 3, 9 and 12 are performed by Mr Montgomerys staff.

Validation of moist steam Steriliser.

Validation of standard loads is going to be very time consuming unless the steriliser are essentially used for such tests, to the exclusion of routine production work. i.e. Taken out of normal service for a week each machine, and provided that staff can be available to ensure proper maintenance of equipment during this period. The sensible way to tackle this problem would be over a period of about 3 months during which time essential equipment be treated as priority for test.

Validation of steriliser is usually the responsibility of two distinct operators of people.
Routine daily tests of basic measure are attended by the user i.e. operator and supervisor. More complicated tests such as validation of standard loads and commission testing is NOT left to the user since bias may be introduced i.e. the user may be tempted to establish test

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conditions which are favourable to them.
On the NHS, thermocouple tests of sterilising equipment are routinely performed by the Hospital Engineers staff. In private industry this task is performed by the Q.C. section.
During the past 10 years of operation, no commission tests have been performed, routine daily/weekly tests have been undocumented and mostly not performed. Documentation was non existant, Periodic tests were meaningless and results have never been reported to the T.S.M.

Wrapping of equipment.

Responsibility for wrapping has been divided between production departments and Technical Services, due to inadequate staff levels and space in T.S. area. During the visit by M.I., those items of equipment not properly wrapped, were mainly prepared by production units who complete their own assembly and wrap operation. Two main areas of complaint were noted:

i Equipment from C.F. lab, particularly filters.
ii Clothing for use in sterile areas.

A meeting of users will be arranged for week ending 13/3/81 to discuss correct procedure.

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Problems in T.S. area when considering priorities of work :-

1. Considerable time has been, and still is, being expended on management of staff.

2. Mrs Plummer is learning to supervise this type of service unit and is making progress. She was not conversant with the equipment or techniques prior to joining B.P.L. As a part of her training Mrs P. has visited Edgware CSSD for instruction and advice.
   Additionally there has been the need to have the T.S.M.'s office with Mrs P. This has been good from the viewpoint of regular meetings and induction, however it does cause increased use of the office by other staff and this leads to difficulty over continuity of work effort on my part.

3. Staff levels in T.S. are inadequate. A fully centralised service cannot be performed with present structure and it is unlikely that we could house sufficient staff to do so even after completion of MARP/01, let alone in present accomodation.

4. The T.S.M. has had several demanding responsibilities, all priority to deal with in addition to staffing.

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i Investigate, commission and organise S.O.P. operation of the new bottle washer.

ii Take over and validate hot air sterilising ovens. Initiate documentation for bottles washed on machine and oven sterilised, with batch identification.
Arrange scheduled cleaning of new machine.
STAFF LEVELS IN T.C. ARE INADEQUATE FOR THIS SERVICE

iii Establish S.O.P for receipt of infected wastes and safe disposal of same.
PREVIOUSLY NO CONTROL OVER THESE PRODUCTS

iv Wet nurse Crathalls cleaning managers, (3 in 7 months), during the formative first years service. I estimate that 50% of my time has been spent on documentation, control of contract and in particular trying to get BPL staff involved at all levels.

v Clean room laundry & Linen Room to organise shortly.

Equipment

Our sterilisers are inadequate by M.I. standards. BPL seem to have accepted that we have three persons load sterilisers because the manufacturers described them as such when supplied.
The sterilisers do not conform to B.S.; in the case of the two largest machines it is incorrect to describe them as such, these machines are not suitable for washed instruments.

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These two machines, the most useful as regards capacity, are best described as down displacement with a good vacuum assist and air drying.

The majority of the process equipment used in BPL process areas does not technically need to be stainless, and only needs to be clean and free from rust. Washing in such circumstances helps to remove the lubricant and particulate loads added to the unstable product. - This may be desirable but is not essential to production.

The stainless are therefore not ideal but in my opinion adequate for the basic task asked of them.

It should be stressed that we do not terminally sterilise any of our products.

Mr Vallet was asked if we should budget in 1981/82 for new B.S. stainless to the appropriate Parenteral Standard — however it was suggested that with doubt about commercial involvement, the continued possibility of DHSS funding and perhaps plans for a new building, that it was not appropriate to do so.

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Summary:

1. The inspectorate were critical of our Auditors, lack of thermocouple validation, working techniques and of the congestion in T.S. area.

   i It was not considered appropriate to budget for new Auditors when last discussed.

   ii Most of the equipment working criticised by M.I. was prepared by C.F. lab and Terminal Processing staff. We do advise on working techniques but it is difficult to enforce standards unless under our direct control.

   iii Tests and checks of equipment have been increased, although validation with thermocouples remains to be introduced.

   There can be little doubt that at the extremes of temperature/time exposure used by BPL, equipment will be sterilised.

   Thermocouple tests will commence on 10/3/81 putting the wires via door seals. This preliminary work to be followed by tests via the proper entry ports on 16/3/81 when Vacuum Engineering Commission the compression joints.

   It should not be considered that T.S. underestimate the need for more accurate validation. The deficiencies of the system cannot however be tackled overnight bearing in mind deficiencies in staff numbers and experience.

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11 It is not possible to employ sufficient numbers of staff within the T.S. area, thus ensuring a complete service, mainly due to lack of space. We have been criticised for congested work areas. MARP/01 will provide marginal relief with reference to congestion.
Additional staff levels have been discussed with administration although there is a need to agree grades of pay for new operatives. (see action list).
As soon as Mr Shanks (stewardesses) retires, in May, it should prove possible to operate more frequent stewardess runs with smaller more controlled payloads. Restructuring of old established work patterns will lead to greater flexibility and will also ease congestion.

GRO-C: Mr Leavens

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Action List.

1. Varley Engineering to commission extension joints 16.3.81

2. PSL To validate some loads with effect from 10.3.81 by use of Chesil equipment, putting thermocouples through chamber door seals.
   Full validation tests to commence 16.3.81

3. Arrange notes, meeting & demonstration of working techniques for CF Isle and T.P. Isle. (asap).

4. Additional staff requirements. Establishment.

   Sterilisers — 2 operatives (inc BPL) for moist & dry heat equipment. 09.00 to 17.30. } Existing

   Sterilisers / Clean Laundry — 2 operatives (Inc. Media) 09.00 to 16.00 } One addition to existing

   All at ICS grade 0-2-4.

   Supervisor for Sterilisers / Stills / Ovens 09.00 – 17.30 At ICS grade 10 } One addition to existing.

   Process Operatives — 2 operatives 09.00 – 17.30 for special responsibilities Ex CF & T.P. areas. Wash/assembly equipment Washing machine operation Plasma disposal GRADE TO BE AGREED } Two additions to existing

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