

Mr Harley

GRO-C

7/9/79

IMPROVING MANUFACTURING CONDITIONS AT BPL

- It is a view of the importance of these discussions you may like to have an opportunity of looking through the record before it becomes a working document.*
1. We met Dr Lane yesterday to talk about the short term measures which will need to be taken following the publication of the Medicines Inspectors' report. We assumed that there would be no fundamental changes following the consideration which is due to be given to the Report in the Medicines Division but acknowledged that there were a number of factual inaccuracies in the Report which would have to be put right.
 2. Dr Lane opened by stating that he estimates that if the unit was to function at its present level, something like £300,000 would have to be spent on plant replacement over the next 4 years. He drew attention to (most of it in the early part of this period) the difficulties he was experiencing in recruiting staff suggesting that if staff continued to leave at the present rate this factor alone would frustrate any attempts to upgrade BPL. He has lost 4 members of staff to commerce in the past year. Dr Lane pointed out that at the present rates of pay they were unable to recruit even boilermen and fitters and at the present staffing level, routine preventive maintenance of plant was quite out of the question. There was also a limit to what could be done to improve environmental control. He thought that to bring the staffing levels up to those required to maintain the present level of production but to standards approximating to those advocated by the Medicines Inspectors might itself increase BPL wages bill to about £1 million a year. It would, however, be impossible to house them^{staff} in the existing premises.
 3. It was agreed that it was essential to identify these improvements to BPL which could be introduced quickly, and at minimum cost. Documentation, cleaning and autoclave maintenance appeared to come into this category. The Department could provide assistance with the documentation and advice on autoclave maintenance and engineering if necessary and Dr Lane was willing to avail himself of these services. Dr Lane explained that within the limits which he had already outlined, steps were already being taken to remedy many of the deficiencies to which the Inspectors had drawn attention. He was currently working^{through} the Report with the heads of his various Departments and he would be letting the Department have his comments. It was his intention to ask Dr Smith from PLF to look at all documentation for coagulation factor production at the two laboratories and to bring it up to scratch as far as possible. Dr Lane pointed out, however, that at the present staffing levels it was one thing to introduce documentation and another to enforce it. Suitable documentation was also being worked out for the other departments but it was unlikely that very much could be done to improve the technical support services (which Mr Leavens manages) unless "stop-gap" were to go ahead and money was made available for additional cleaning services.
 4. Dr Lane thought it unlikely that much could be done to improve the main air conditioning filtration plant radically without closing down the factory for several months, but they were already considering how the laminar flow cabinets might be improved. The aim was to introduce preventive maintenance of the air filtration plant but once again, they would need additional staff to do so.

Proposals which Dr Lane had already outlined to the Scientific and Technical Committee for improving the bottle and cap used to pack PPF, and which he... would cost at the next meeting, represented an important step towards product safety since the present bottle and screwcap has been shown to be unsatisfactory. The installation of a new bottle-washer would also help in this connection. The cost £40,000 and had been included in stopgap. The addition of 5,000 cubic feet of cold storage would also help and Dr Lane agreed that it would be advantageous if this could take the form of modular units rather than built-in cold storage rooms. The modular storage could be isolated and used elsewhere

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when required. At present there was no fall-back cold storage capacity whatsoever.

Dr Lane explained that the improvement to the freeze drying plant and workshop and the removal of the small workshop area from the terminal processing area, which the Department had agreed should go ahead, were themselves important contributions to product safety. He thought that it was very important that the main improvements to the terminal processing area proposed in "stop-gap", where finished products and incoming goods were inadequately separated, should go ahead. Stopgap would remedy many of the deficiencies identified at this end of the laboratory.

6. Other important requirements were to ^{move} ~~move~~ the microbiology department from its present location, to improve the security of the bulk storage and to rotate stock. Although the Inspectors had not commented on the state of the sewage plant it was known to be in a poor state of repair and Dr Lane thought that it would be unwise to delay the repairs. He was hoping to improve the standard of the protective clothing and to ensure that better use was made of what was available. Dr Lane felt that there was an urgent need for a "dirty" autoclave (£30,000 + installation and building costs) He thought that it might be possible to manage without a 3rd York compressor (£30,000 +) if BPL was to move into new premises in about 3 years. Other major items needed was a mainswater still (£50,000 +) to bring the water used in the laboratory to a more acceptable level.

Summing up, Dr Lane said that accepting that there was to be no immediate attempt to increase the output of the laboratory and that the first aim must be to bring current levels of production more in line with the Inspectors recommendations, something like £3.4 million would have to be spent on building and equipment, much of it within the next year. The expenditure ~~was~~ ^{will} have to be matched by an upgrading of staff if the improved procedures were to be devised, executed and supervised.

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