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CENTRAL BLOOD LABORATORIES AUTHORITY

GRO-C

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Dear David,

As requested I report my findings on the recent confusion we generated relating to plasma weight and 8Y yields.

Plasma Weight

Plasma is received from the RTC's in a variety of packs normally at a temperature of -40°C. Obviously only Gross Weight (= plasma plus packaging) can be recorded at this stage. RTC's do not weigh their consignments to us.

The Nett Weight (= plasma only) is established by taking gross weight and applying correction factors appropriate to the type of pack containing the plasma. This process is computerised and is a sufficiently reliable and accurate system. Nett weight is generally 15% to 18% lower than gross - again depending on the packaging used.

There is a further measure known as the Process Weight which is the Nett Weight less any damaged or compromised packs (always recorded) and less plasma lost adhering to the plastic packs following stripping (not susceptible to measurement). Process Weight is typically around 7% less than Nett Weight. Yields are calculated on the basis of process weight.

Up to August 1987 Nett Weight was the only measure circulated when referring to plasma inventory.

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All interested parties eg. DHSS and RTC's, CBLA were notified on the basis of nett weight.

However, in response to audit concerns the 'plasma stock report' issued monthly by Materials Management from August 1987 onwards was based on Gross Weight. Unfortunately as this change received insufficient publicity, some staff (including myself) still read the plasma stock report as nett plasma weight.

In most situations this did not matter but it has caused errors in inventory valuation and assumptons on physical stock. Unfortunately it was a gross number that was reported to the Medical Sub-Committee of the Plasma Supply Working Group on 28th April. Of the 500 tonnes gross reported, only 380 tonnes is relevant for 8Y production.

It happened that Richard Lane reported the 500 number but had anyone else from CBLA attended the meeting it is probable that the same number would have been reported. The difference of 120 tonnes is about three months inventory at current usage. I can appreciate the inconvenience caused by the incorrect number and apologise unreservedly for the occurrence.

However, this episode must not be allowed to obscure the magnitude of the failure in planning for the appropriate level of plasma for the new factory.

Even though the new Production Unit is two years late in starting we are still facing the prospect of a plasma shortfall and are being asked to throttle back production to 480 tonnes per annum when we were about to move to 550 tonnes per annum.

Actions

1. Plasma stock report to revert to a nett weight basis commencing this month.

2. Review minimum plasma inventory levels to help reduce rate of acceleration of plasma demand.

3. Continue with programmes designed to improve yields in Building 27.

4. Hold production level at 480 tonnes per annum.

Yields

I have perused the minutes of the Medical Sub-Committee of the Plasma Supply Working Group (28th April 1988) and the subsequent Discussion Document (25th July 1988).

In summary, the Discussion Document used a factor of 180 iu/kg to calculate future plasma requirements and noted that current yields averaged 166 iu/kg. The minutes record a battery of yield numbers, from 210 iu/kg to 140 iu/kg and refer to "process" yields and "nett" yields.

On the basis of the minutes, using a factor of 180 iu/kg is defensible as is 160 iu/kg or the existing performance of 140 iu/kg for that matter. Again the issue is clouded by reference to both "process" and "nett" yields. We concede the accusation of imprecision.

At the subsequent meeting of the combined Sub-Committees, CBLA Members considered that 180 iu/kg was overly optimistic and suggested that 145 iu/kg be used for planning future plasma requirements.

A further development since then is the recommendation that the notion of "process yield" be abandoned, and yields should be calculated on the input of Nett tonnage and not Process tonnage as hitherto, hence the recent basis of 130 iu/kg to calculate forward plasma requirements.

This is not without its disadvantages but it is vital that there be unequivocal standards for inventory and yield and we will adhere to these.

Our position has not been helped by our limited experience in the new building or our determination to improve yields. The advantage of the new yield standard is that it puts us on "as now" basis for calculating future requirements.

The subsequent news on yield can only be good, provided it is not necessary to insert additional viral inactivation or purification steps.

Summary

CBLA has been accused of generating an unnecessarily high fog index in relation to plasma stocks and yields. There is some substance in the complaint and some mitigating circumstances. We render our apologies accordingly and affirm that it will not happen again.

Yours sincerely

GRO-C

B J Crowley
Chief Executive