

Microbiological Reporting System Specification:

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Overview:

The specification is to help develop a system for recording microbiological results for clean rooms and cabinets within clean rooms. The fundamental idea behind the system is that data will be entered into the system once and then a number of different reports created automatically. Data must also be searchable and exportable so that it can be interpreted in different ways.

Specification:

The system must meet with the following specification:

- The system must be a Windows based system that will sit on a MSSQL server.
- The system must be user friendly and easy to understand and quick to learn.
- The system will need to be fast when starting up and running and must not drain PC resources.
- The system must be stable and secure.
- The system may need to be networkable.
- The system will need to be fully tested before it can be released to the trust, and when the first release goes live for a set period of time data must be entered onto the system and recorded using the paper based system so that data integrity can be confirmed.
- The system will have a similar look and feel to the Emergency Box Management (EBM) system that BRI are currently running.
- The basic principal of the system is that data is entered once, and reports automatically created using this data.
- Data entry must be very simple and involve as few as possible mouse movements, in order to speed up data entry.
- The system must record the batch numbers for each media used on the system.
- Rooms must be setup with Settle Plates, Biotest Strips, Contact Plates and Finger Touch Plates. Each plate must have a location, zone, warning limit and action limit.
- All plates must record an Plate Batch Number, Operator, and the Growths recorded. Settle Plates must also record the length of time they are exposed for.
- The system will re-calculate the warning limits and action limits for settle plates according to their exposure time.
- Biotest Results are recorded once a week, the first week of each month this will be a SDX Biotest and the other weeks will be a TC Biotest. Settle Plates Results are recorded at the same time.
- If a plate has more growths on than acceptable then it needs to be sent away to the labs to be tested fully. When the plate is sent off to the labs it is given a unique ID this must be recorded in the system. When the plates return from the lab, the unique ID will be entered into the

system and the user will then enter the results on a form, these results will then be matched up to the specific plate using the unique ID. (Sent to Micro for ID)

- If the number of growths recorded by the lab differ from the original reading then, the original reading must still stand.
- Each plates growth types must be recorded, e.g. MEG, there is no need to record the number of each type of growth.
- Growth types need to be programmed into the system so that drop down menus can be used to select the growth type, there removing user error by the wrong abbreviation of a growth being entered.
- Growths need to be flagged up on the screen as the organisms are entered, these include Normal / Expected, Unusual, Possible Problem, Serious Product Threat.
- Ability to record no production days in certain rooms. This information will need to be printed on the reports.
- Specific results should be editable in case a data entry error has occurred. This however must be secure and a comment will need to be attached explaining why the result has been edited.
- The data must be searchable, so that it can be interrogated in any possible way needed.
- Graphics should be able to created from the system, the type of graphs and data to be displayed are shown below in the graphs section.
- Data should ideally be exportable to excel or other spreadsheet format.
- The system must have a section where users can go to and review the list of Exception Reports that are ready to be printed out. The Exception Report must look important and attract the attention of the room operator when they receive it. Exception Reports must have room for the QA Pharmacist to make their comments, and room for reply by the room operator. The QA Pharmacist comments could be programmed into the system as comments / actions are often the same.
- Results will need to be printed out monthly reports. The reports should highlight any out of range results. The reports will be based on the Quarterly Reports produced by BRI, the reports will also be designed to show a maximum of 50 plates.
- The reports must be colour coded showing Critical Zones, Product Transfer Hatch and Background Environment in different colours. Reports will need to be interpretable whether printed in black and white or full colour.
- Users will be required to log into the system so that results are stored securely and that any data input can be traced back to a specific user.
- All system data will need to be easy to backup either to the local machine or in a way that it can be removed from the machine.
- The system must meet all the requirements set out in this specification.

Graphs:

This list shows the type of graphs that need to be created using the system and the data to be shown.

Line Graphs: Individual Locations (Rooms, Cabs, Isolators etc).

Specific Operators.

Average contamination. growth per location.

Pie Chart: All Biotest Strips

All Contact Plates

All Touch Plates

All Settle Plates

The pie charts should show segments of No Growth, Growths below limits, Growths equal to limits and Growths above limits.

Development Issues:

At this moment in time there are a few issues that I can see with developing this piece of software, these are details below:

Monthly and Quarterly reports may become messy as large quantities of data will be on them.

Methods of export data may be difficult because different rooms / cabinets will have different data-sets.

Allowing users to customise reports so that they can have set actions on may be complicated.

These are the main issues but there are ways to work around them as long as time is spent in the early stages planning the system carefully. However the bulk of the system development is relatively straight forward to develop.

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