EMPLOYMENT APPEALS TRIBUNAL

CLAIM(S) OF: CASE NO.
EMPLOYEE *(claimant*) UD927/2010
MN876/2010

Against

EMPLOYER *(respondent)*

under

UNFAIR DISMISSALS ACTS, 1977 TO 2007
MINIMUM NOTICE AND TERMS OF EMPLOYMENT ACTS, 1973 TO 2005

I certify that the Tribunal
(Division of Tribunal)

Chairman: Mr N. Russell
Members: Mr J. Browne
Ms S. Kelly

heard this claim at Wexford on 31st January 2012 and 23rd March 2012

Representation:

Claimant: MM Halley & Son, Solicitors, "Presentation House"
Slievekeale Road, Waterford

Respondent: Mr. John Farrell, IBEC, Confederation House, Waterford
Business Park, Cork Road, Waterford

The determination of the Tribunal was as follows:

Background

The respondent operates a medical devices manufacturing company, producing guide wires, which are used in surgical procedures. Safety, quality and compliance with regulatory requirements are paramount in this highly regulated sector. The manufacturing process is subject to regular audit to ensure compliance. Staff are aware, through training procedures that falsification of documentation may lead to dismissal as a sanction. It was established that the claimant falsified documentation (breach of Q002) and consequently was dismissed.

Respondent's case

Giving evidence, the Team Leader stated that after a power cut on the 24th November 2009, it was noticed that there was an issue with an order overload, which can have very serious consequences for the company, including losing their licence to operate. In this case, following the power cut, the orders were sorted and production continued. The Team Leader reported the matter to the Supervisor.

Under cross-examination, the Team Leader stated that 200 guide wires per tray is allowed and disagreed that the procedure had been changed to allow for more guide wires per tray. There is a high degree of trust given to employees as the procedures are very defined and staff are well trained. There would be very little direct supervision required. The Team Leader denied that he ever told the claimant to take a number of guide wires back from the clean tank.

Under re-examination, the Team Leader explained that every basket could not be checked. Staff are well trained on procedures and there is a certain amount of trust involved.

The clean tank check sheet of 24th November 2009, showing line clearance, was opened to the Tribunal. The orders had been verified as being done but had in fact been locked into the system when the power cut happened.

In reply to the Tribunal, the Team Leader stated that each wire is not labelled. The wires go in bundles and a magnetic pen will pick up any stray wires.

Giving evidence, the Packaging Supervisor stated that they started work on 24th November 2009 at 6am. At 6.30am the power failed and then resumed. About 7.30am the power failed again and employees were sent home. The claimant decided to go back in and clean the tank. The Supervisor was concerned for her safety and followed her in. No employee had been asked to go back in. The claimant said she did not want to leave a mess for the next shift. Later the Supervisor received a call from the Team Leader to say the number loaded was incorrect and that line clearance had been signed off on. The next day the claimant came to the hatch and said "she knew" i.e. that it was incorrectly done. The quantities and line clearance had been breached. The claimant said "I was stupid".

Under cross-examination, the Supervisor stated that he had been working with the claimant for three years and that her work ethics were good. He said the procedures tell you what to follow. He was not aware that the general consensus was that the tanks accommodated more guide wires. It was put to the Supervisor that the claimant had been previously asked to fix labels onan order as there had been a misprint and that the Supervisor had said "heads will roll" but thatno-one was dismissed as a result of that incident. The witness stated that he was not aware ofthis but that what was being outlined was a genuine mistake and that was a distinct difference tofalsifying documents. The witness was not aware of any other incident comparable to the claimant's.

Under re-examination, the Supervisor confirmed that employees were aware that a breach of Q002 leads to dismissal. There was no bonus system in place in relation to quantities but there were daily targets in place. The target was disregarded the day of the power cut. Nothing happened if the shift target was not reached.

Giving evidence, the Senior Supervisor of Packaging and Shipping stated that staff knew that a breach of Q002- deliberate falsification of documents resulted in dismissal. The system is based on training and trust. The witness delivers training, along with the site Director. The day after the power cut, he was informed of the incident and he went through the issue with the

claimant and then informed the HR Director. There was an acknowledgement by the claimant when she replied "she knew".

Under cross-examination, the witness stated that the claimant appeared to know that wrong had been committed. He did not have notes to say he discussed the line clearance sheets with the claimant. The claimant had said she fully loaded the carrier and trays in case the power went again.

In reply to the Tribunal, the witness stated that the Q002 training was the same presentation each time it was given. In relation to empty trays, if you do not have an empty tray, there is potential for a guide to be lifted from the trays. No member of staff has ever been penalised in relation to targets.

The Human Resources Manager gave evidence that she has worked for 18 years with the respondent company. In that time the company has expanded from employing nine employees to employing over 700 employees. The Food & Drug Administration (FDA) approval means that the respondent can ship to US hospitals. The company is currently seeking approval to enter the European market.

The guide wire is used in angiograms and for this reason both the sterilisation and the size of the wire must be verified and the label on the packaging remains on a patient's file for seven years. Last year the respondent company had 13 audits.

The FDA can apply different levels of sanctions on the respondent company. In the case of a minor matter the FDA sends a letter asking for the matter to be rectified within 6 days. A more serious sanction could mean a product recall where the factory has to stop shipping until the issue has been resolved. This has happened to other companies in Ireland.

The Q002 standard operating policy was introduced in 2008 as the regulatory process was becoming tougher all the time. A training presentation was given to staff about the seriousness of signing documents when work was not completed or on behalf of another employee. Each of the 700 employees receives six-monthly training on this procedure. The training presentation also informs staff that it is company policy to dismiss if a breach of Q002 is found to have occurred. It is a serious policy but it has to be as the customer/patient could be at risk. It is known within the company that a breach of Q002 will lead to dismissal and there have been other dismissals for breaches of the policy.

The claimant signed that she had received the training on Q002 and on clean tank standard operating procedures. As previously stated the training was carried out on a six monthly basis and the claimant received the most recent training in the three weeks prior to this incident.

The claimant telephoned the human resources department on the afternoon of the 24th November and asked for the trays in the clean tank to be put to one side for her to finish her work on them the following day.

The Human Resources Manager was subsequently informed that a serious issue had been discovered by the second shift in the clean room in that the trays were discovered in the tanks. The trays were also overloaded and there were no empty trays placed in the clean tank even though the claimant had signed off that they were placed in the tank. As a result the product had to be re-washed, cleaned and processed.

The claimant was informed at the meeting on Friday, 27th November 2009 that she was suspended with pay for three days while a suspected breach of Q002 was investigated. The claimant said that she knew she was stupid to do what she did. The claimant did not seem to be in shock at the meeting but did not offer an explanation. While a quota is in place, no action is taken if a quota is not reached and there are days when the target is not reached.

The Human Resources Manager investigated the matter and spoke with the supervisors as part of this investigation. She also examined the documentation and training records. It was found that the baskets were loaded into the clean tank and the door remained closed due to the power cut. When the power returned the baskets were found to be overloaded. Empty baskets have to be placed in between the filled trays to stop the product falling. This was introduced as an additional safeguard. But there were no empty baskets placed between the tanks despite the fact that the claimant had signed off that this had been done. Even scrapped wires have to be accounted for and for this reason it is in the standard operating procedure to place empty trays in the tank. The claimant had signed for something that had not been carried out which was a breach of the Q002 standard operating procedure.

The claimant was informed at the meeting on the 2nd December 2009 that the company had no option but to dismiss her due to a breach of Q002. No justification was put forward by the claimant at this meeting.

Claimant's case:

It was the claimant's evidence that her employment with the respondent company commenced in January 2005. Some three months later she began her duties in the clean tank area and she enjoyed this work. The claimant was responsible on her shift for manning two clean tanks while her supervisor was nearby in the hatch area. Sometimes the claimant found she was under pressure depending on the number of orders received at any one time. However, the claimant stated that she worked in the clean tank area for over four years and she was confident that she could manage any orders received. The claimant was aware that the items she was cleaning were for people's bodies. This was always referred to as the most important thing as part of Q002 training.

On the day of the incident, when the power went out for the first time, the claimant had verified the documentation for the order and was burred into the order. It was explained to the Tribunal that to bur means to scan in a manner similar to scanning a bar code. The claimant put extra wires into each basket and then realised that she had burred the order and had "stupidly put extra wire guides in the tray." The claimant stated that there were meant to be 200 guide

wiresto a tray but she had placed more than this on each tray. Because the claimant was burred intoit she was trying to get the order completed. The claimant stated that there was no consequenceto her of not getting all of the order done.

The claimant was shocked when she was told that the matter was being considered a breach of the Q002 standard operating procedure. She accepted that she had received training on this issue and she understood that the penalty was instant dismissal. However, the claimant outlined some instances to the Tribunal which she believed were similar to her actions and stated that those employees had not been dismissed. The claimant was expected to be sanctioned but did not expect the sanction to be dismissal. The claimant gave evidence pertaining to loss.

In reply to questions from the Tribunal, the claimant said she did not have it in her mind to amend the line clearance documentation that she had completed.

Determination:

It is most unfortunate that the claimant who was clearly a decent hardworking woman lost her position with the respondent company. The claimant was unable during the investigative or disciplinary process, nor, indeed before the Tribunal to provide any plausible explanation for her actions on the 24th of November 2009 particularly in light of her excellent standard operating procedures training and her clear understanding of same.

Standard operating procedures have to be sacrosanct in a business dealing with the production of medical devices. There is no room for operatives to unilaterally depart from those procedures.

In this instance the claimant accepted in evidence that she had her Q002 training, completely understood that any falsification of documents would result in dismissal, had falsified her line clearance check sheet for the clean tank on the 24th November 2009 and had not intended to amend the form to reflect her actual actions on the day.

In the circumstances the Tribunal finds the dismissal of the claimant to have been fair in every respect. The claims under the Unfair Dismissals Acts, 1977 to 2007 and the Minimum Notice and Terms of Employment Acts, 1973 to 2005, fail.

Sealed with the Seal of the

Employment Appeals Tribunal

This _____

(Sgd.) _____
(CHAIRMAN)