EMPLOYMENT APPEALS TRIBUNAL

CLAIM OF: CASE NO.
EMPLOYEE -*Claimant* UD333/2011

against
EMPLOYER -*Respondent*

under

UNFAIR DISMISSALS ACTS, 1977 TO 2007

I certify that the Tribunal
(Division of Tribunal)

Chairman: Ms B. Glynn

Members: Mr P. Pierson
Mr O. Nulty

heard this claim at Longford on 18th January 2012 and 9th May 2012

Representation:

Claimant: Ms. Alison Haugh B.L. instructed by Chambers Law Solicitors, "The Lamp," 1 Bridge Street, Kilcock, Co. Kildare

Respondent: Mr Terry MacNamara, IBEC, 3rd Floor, Pier 1, Quay Street, Donegal Town, Co Donegal

The determination of the Tribunal was as follows:

Background

The manager of the plant (DS) explained that it was a small operation consisting of 5 or 6 people manufacturing drip bags for hospitals. The company is licenced by the Irish Medicines Board. TPN bags are produced under strict procedure, depending on the requirements of the individual and at the request of a hospital.

He described the operation as the most critical and dangerous operation in Ireland. The bags are made up of various vitamins, salts and other vital ingredients and are filled through pumps in a controlled clean room. There are strict guidelines for quality assurance. All products must be made to the same quality and standard.

Respondent's Case:

The claimant as head of production had responsibility for production and manufacture of the product. He reported to DS. They had a good working relationship and the claimant was a good worker. Two people work together to ensure human error does not occur, everything is double checked. At the end of each day all sections are destroyed and new tubing is set up for the next day. A pump rotates and passes the solutions through flexible tubing. As the system warms up the pump has less to do. The system is calibrated a few times each day to ensure measures are accurate. It has to be done first thing each morning and after each break. This is standard operating procedure and has to be documented. The calibration is to ensure that accurate measures of solutions are in each bag.

If an incident (deviation) occurs with the calibration the quality control department needs to be notified immediately and a note put in the daily incident log.

An incident occurred on 10th September 2010, a day when DS was not working. He received a call from his deputy IA to say a deviation had occurred. The pump was not calibrated after a break and there were concerns over the bags for that day. DS later received a call from the claimant to say he had not calibrated after his break. He was surprised that the claimant rang him. DS asked about the incident and if there was anything else he should know about. The claimant said "no". DS then asked him to give the phone to IA and she confirmed that he had not calibrated but also that he had not submitted any paperwork for quality control. It was a colleague who was working with the claimant on the day who told IA of the incident and IA put aside signing off on the bags as she felt it was a critical deviation.

Following an investigation DS held a meeting with the claimant on the 14th September to go through the details. The claimant said he did not follow procedure. As this was a third occurrence of breach of procedure the claimant was advised that the matter would have to be discussed further with management. The claimant did not request any further meetings and was suspended on full pay on 17th September.

A further meeting was arranged for the 23rd September. The claimant did not bring representation and was asked if he wished to proceed. He said he was aware of the seriousness of the situation but the tubing had been stopped earlier than usual on the day in question so it would not have been as warm as it might usually be.

The claimant was fully aware of his responsibilities, had two previous disciplinary incidents and had misrepresented what had happened. The respondent considered his actions as a breach of trust and that he had put the business t risk. The claimant was dismissed on the 29th September.

During cross-examination DS said that everybody had to follow standard operating procedure. On the day the incident occurred he was not aware of anything unusual, it was a quiet day with only five bags produced. Regarding a previous warning to the claimant DS stated that it was a serious disciplinary, it was put in writing and posted to the claimant. This incident was a stand-alone incident and was deemed by the respondent as gross misconduct.

DN gave evidence that at the time of September 2010, she was employed by the respondent as a compounding technician making the drip bags as outlined by the respondent's previous witness. As the solution passes through a patient's heart it is necessary to ensure the quality of the product.

Two employees work together in the clean room to ensure the quality of the product so as one may

double check what is produced while the other person ensures procedures are correctly followed. Standard operating procedures (SOP) are followed step by step to ensure each product is made consistently. SOP 2099 is the procedure which informs how the environment and the pump should be set up for making the TPN bags. The calibration of the pump is very important as the pump heats up during production and subsequently cools down afterwards. When the pump heats it may change so that the quantities can vary if it is not calibrated properly. If the pump is not calibrated it is not possible to be certain of the quantity in the bag. The SOP states that a check calibration will be performed by purging 40ml of WFI after each break; this reading will be recorded and checked versus specification. After calibration a quality or QA bag is produced for quality assurance purposes. A deviation is deemed to have occurred if the procedures outlined are not followed.

DN was working in the clean room with the claimant on the 10th September. The pump was set up and a calibration performed with the production of the QA bag in or around 10am. As no production order was received they exited the clean room at 10.30am for a break. As a production order was due in around 11.30am, DN and the claimant returned to the clean room. DN noticed that the claimant was about to start the process of making TPN bags and she queried with him about carrying out a calibration but he assured her that they did not need to do it. DN believed this to be incorrect and that the claimant was not adhering to SOP 2099. She told him to discard the TPN bags as what he was making was done without a calibration being carried out. The claimant did not respond. As two people must be present when the bags are being produced DN waited until production was finished. She then exited the clean room and telephoned the quality assurance person (IA) and informed her that TPN bags had been produced without calibration taking place.

On Monday, 13th September, DS informed her that the matter was being investigated. DN provided a statement as part of the investigation.

During cross-examination it was put to DN that the SOP in question was open to interpretation and that the break referred to in the procedure was actually a break in production. DN replied that a calibration was performed after each and any break. While a QA bag had been produced that morning, the pump cools down when it stops and a recalibration is required. DN confirmed it was the claimant who had authored SOP 2099 and he was the person who had authorised any amending versions.

IA gave evidence that at the time of September 2010 she was the quality assurance technician with responsibility for batch release. If a deviation occurs from the SOP the deviation needs to be raised and explained.

IA confirmed that a QA bag was produced in or around 10am on the 10th September. Later that morning she was approached by DN who stated that she was concerned about a deviation. IA examined the deviation log but there was no record of a deviation having occurred. When DN outlined her concerns, IA knew immediately that it was a deviation and retrieved the production record before the staff left the clean room. The claimant did not approach IA regarding the issue. IA spoke with the claimant and told him that DN had raised an issue with her that a deviation had occurred but was not recorded. IA requested that the claimant complete a deviation report and he acceded to his request. The deviation report completed by the claimant was opened to the Tribunal. IA told the claimant that there was a question over the production for the entire day as a step in the SOP had not been carried out but the claimant dismissed what she said in this regard.

IA completed an outcome of deviation report and found that the TPN bags produced could be released due to the other checks that had been performed. As part of her role she must inform DS

of any deviations and get his approval regarding the deviation. After the matter was raised with DS he spoke to her as part of the investigation.

IA attended the disciplinary meeting on the 23rd September 2010 as a note taker. At the meeting the claimant agreed with the issues raised and the actions taken. The claimant did not indicate that there was pressure on him to sign the document put before him.

During cross-examination version 13 of the SOP was opened to the witness. IA stated that an SOP can be drafted and training provided but it is not a final SOP until it is implemented on a certain date.

The Managing Director of the respondent company gave evidence to the Tribunal that calibration is fundamental to the manufacturing process and the quality of the bag produced. The bag is usually for very sick patients for whom it is the only source of food. If the pump produces the wrong quantity of ingredients it can have serious, and even fatal consequences as outlined by the Managing Director.

The Managing Director heard the appeal at which the claimant was represented by a solicitor. The claimant's main issue was that he did not accept a deviation had taken place. At the appeal hearing the claimant did not raise any issue of being placed under any duress at the earlier meetings. Initially the claimant did not accept that a deviation had occurred even though it was raised twice with him in the clean room by DN and he had completed a deviation report. However, after discussion with IA and DS the claimant did accept that there was a deviation. The claimant's lack of communication with IA regarding the incident and his changing position on the deviation werethe Managing Director's reasons for not overturning the decision to dismiss the claimant. Therewas a breach of trust in the claimant's position.

During cross-examination the Managing Director stated that there was previously a disciplinary issue involving the claimant but this was not taken into account when reaching his decision on this matter. A minor deviation was deemed to have occurred in relation to the bags however the critical deviation was the claimant's failure to communicate the deviation.

Claimant's Case:

It was the claimant's evidence that he holds a Bachelor of Science qualification as well as a number of higher diplomas. During his employment with the respondent company the claimant wrote a number of procedures including SOP 2099. The procedures were to be audited by the Irish Medicines Board and the claimant revised SOP 2099 a number of times.

When the claimant wrote SOP 2099 his understanding of the calibration procedure was that when the pump had finished running and a break followed, a calibration would have to be carried out. On the morning of the 10th September the first thing the claimant did was calibrate and send a QA bag to the lab but nothing else was produced. The claimant understood the pump to be in a calibrated state up to that point.

The 10th September differed from other days as on other days production usually followed the production of a TPN bag without a stoppage in the interim. What had occurred on the 10th September was outside of the SOP. When the SOP was written it did not take into account breaks of this nature and the claimant raised this with DS.

When his colleague DN queried about whether they needed to calibrate or not the claimant said they should check the SOP. The SOP states that if there is a break, calibration is required but it also states that the pump should be calibrated post lunch and at the end of production. Given this, the claimant informed DN that they could proceed without recalibrating. In addition the claimant stated that there were certain allowable percentages and on this occasion all the bags were well within those specifications.

At the end of the production run the claimant exited the clean room and IA told him that the pump should have been re-calibrated. The claimant stated that if a quality assurance member of staff raises an issue then the product cannot leave, regardless of whether or not the claimant agreed that a deviation had occurred. As a result the claimant wrote the deviation report to prevent the product from leaving the premises; this was in line with his training.

DS was telephoned and the claimant told him that he and IA had an issue. The claimant outlined that he thought the SOP was followed. DS requested the percentages for the bags and when the claimant provided DS with them DS told him that it was a minor deviation and that the product could be released and the deviation closed off.

At the subsequent meeting on the 14th September the claimant explained to Slattery that no orders were received after the pump was calibrated and he raised the fact that the SOP was silent on this issue. DS did not seem to agree with the claimant and he stated that an investigation would follow.

The claimant subsequently attended the disciplinary meeting which was followed by the letter of dismissal and the subsequent appeal process. In his evidence the claimant stated that he did not agree with the contents of the minutes of the meeting of the 14th September and stated that he had signed the minutes at the time without reading the contents of them. The claimant gave evidence of loss and efforts to mitigate that loss.

During cross-examination the claimant stated that often he and DN would wait in the clean room for an order after calibration and on such occasions they did not recalibrate when an order was received.

The claimant stated that he did not change his stance on whether or not a deviation had occurred, he had always stated that what had happened was not a deviation but he had to complete the deviation report as that was the procedure if an issue was raised by the quality assurance personnel.

In reply to questions from the Tribunal, the claimant stated that should the pump not be in use from the previous night then it should be calibrated each morning. No timescale in regard to breaks and calibration is specified in the SOP.

Determination

The Tribunal have carefully considered all the evidence at length, which must be viewed not alone

against the background of rules and regulations in which this industry operates, but also, and more importantly, against the consequences that could result from non-compliance with these rules and regulations.

In particular, and in reaching our decision, the Tribunal have given particular attention to the evidence of the respondent's manager who gave a detailed account of the work involved, and outlined clearly the many checks and balances to be implemented every day to ensure adherence to the strict guidelines and regulations necessary to ensure the quality of their product. In particular, he explained that the TPN bags were made for hospital use, usually in palliative care, to administer food and/or medicine to, perhaps, extremely ill patients so the highest standard of care had to used, as inaccuracies could have potential fatal consequences. He further explained that the company had to apply for a license to carry out their work, which license could be suspended or taken away, temporarily or permanently, if they did not adhere to the standard of care required in the business. The Tribunal were 'walked through' the rules and regulations to be observed in the process of calibration prior to the making up of the bags.

The claimant was employed by the respondent on the 14th May 2007 as Head of Production with responsibility for production and manufacture of the product. He was clearly well qualified for the work and the Tribunal noted that he assisted the respondent in drafting and updating 'standard operating procedures' (SOP) during the course of his time with them which clearly demonstrated his acceptance and acknowledgement that , not alone , were high standards were required for the work, but same required review to ensure they were maintained.

On the 10th September 2010, on returning to his work after an hours break, the claimant did not calibrate the pump prior to operating it. When his co-worker brought it to his attention, he ignored her and continued working. It is clear from the evidence furnished at the hearing that this was contrary to procedure and further clear that the claimant was well aware of this. It was left to his co-worker to report the matter to the quality control department. Neither did the claimant make a note of the incident in the daily production record. Once the matter had been reported to the quality control department by the claimant's co-worker, the quality department refused to sign off on the batch produced as they called it a 'critical deviation.' The claimant did telephone his manager, whowas off that day, to report the incident, though this action was contrary to protocol, but did not give afull account of the matter to him.

It was clear to the Tribunal that the claimant fell short of the standard of care required from him on the 10th September 2010, and that he was aware of this. This is corroborated by the fact that he initially he did not acknowledge that his non calibration of the pump after his break did not constitute a deviation to his co-worker, who had to bring it to his attention, but later accepted that there had been a deviation but labeled it 'minor.' In this regard, the Tribunal noted that the claimant had received two previous warnings in September and June 2009 for non-adherence to procedures.

Part of the claimant's defense was that he did not know he was entitled to representation but it is clear from the evidence furnished at the hearing that he was advised to the contrary. The first meeting was on the 14th September 2010 which was the investigation of the incident. The second meeting on the 17rd September 2010 was merely for the signing of the minutes of the previous meeting by the claimant. However, a third meeting was arranged for the 23rd September 2010 and the claimant was notified of same by letter, which letter strongly advised him to have representation at the meeting. When the meeting commenced on the 23rd and the Claimant attended same without representation, he was again offered representation but declined same. The Tribunal notes that the c

laimant was represented at his appeal of the employer's decision.

In the circumstances, the Tribunal finds that the dismissal of the Claimant was indeed justified in the circumstances, so the claimant's claim must fail.

Sealed with the Seal of the

Employment Appeals Tribunal

This _____

(Sgd.) _____
(CHAIRMAN)