

Florence House Limited

Florence House

Inspection report

The Old Vicarage 17 Church Road, Wanborough Swindon Wiltshire SN4 0BZ

Tel: 01793790727

Date of inspection visit: 10 February 2016 11 February 2016

Date of publication: 20 April 2016

Ratings

Overall rating for this service	Inadequate •
Is the service safe?	Requires Improvement
Is the service effective?	Good
Is the service caring?	Requires Improvement
Is the service responsive?	Inadequate •
Is the service well-led?	Inadequate •

Summary of findings

Overall summary

This inspection took place on 10 and 11 February 2016 and was unannounced. Florence House is a care home providing nursing care for 30 people with a variety of conditions including people living with dementia. On the day of our inspection there were 26 people using the service.

The overall rating for this service is 'Inadequate' and the service is being placed into 'Special measures'. Services in special measures will be kept under review and will be inspected again within six months.

There was a registered manager in post. A registered manager is a person who has registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

We inspected the home on 22 and 29 May 2015 and followed up some of our concerns on 17 August 2015. We asked the provider to take action to make improvements in relation to the management of people's medicines, systems to protect people from harm, records relating to people who were unable to consent to care, supporting staff, quality assurance systems, security and accuracy of people's records. At this inspection we found improvements had been made in relation to the management of people's medicines, supporting people who were unable to consent to care, knowledge of staff relating to their responsibilities to identify and report concerns relating to safeguarding and support for staff.

However we found improvements had not been made in relation to the security of people's personal information, the accuracy of people's care records and systems to monitor and improve the service. We found additional concerns relating to the care and support people were receiving.

The service had not completed the actions stated on the action plan they sent to us following the May 2015 inspection. People's personal information was still stored in an unlocked office which visitors could enter freely throughout the day. People's care records contained information that did not reflect their current needs. Systems introduced to monitor the quality of people's care records had not identified these concerns.

People were not always fully assessed and care plans did not always contain accurate up to date information to ensure people's needs were met. Risk assessments were not always completed and where they were there were not always care plans in place that showed how the risks would be managed. People did not always receive care that met their needs and staff were not always clear about the specific care needs of some people. People had access to activities when the activity coordinator was on duty. However people spent long periods of time with no social interaction on the first day of our inspection when the activity coordinator had a day off.

Throughout the day we saw many caring interactions, however we found that people's rooms were not

always personalised and did not have a homely feel. People's rooms were not always tidy and were left in a condition that did not promote a caring culture.

People and their relatives were positive about the registered manager and proprietor. Relatives told us they were approachable and supportive. However, there were no formal methods to communicate information to people and their relatives. The service did not have systems in place to enable people to provide feedback on the service.

Staff were supported and felt confident to raise any concerns with the registered manager or provider. Staff had regular one to one meetings with the registered manager and there were regular staff meetings where staff were encouraged to share ideas and raise any concerns.

We found three breaches of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. You can see what action we told the provider to take at the back of the full version of the report.

The five questions we ask about services and what we found

We always ask the following five questions of services.

Is the service safe?

The service was not always safe.

Risks to people were not always assessed and where risks were identified there were not always plans in place to manage the risks.

Medicines were managed safely.

Staff were knowledgeable about their responsibilities to identify and report concerns relating to safeguarding people using the service.

Requires Improvement



Is the service effective?

The service was effective.

People were supported in line with the Mental Capacity Act 2005 (MCA). Staff understood the principles of the MCA and how to act in people's best interest.

People enjoyed the food and had a choice of meals. People's dietary needs were met.

Staff felt supported. Staff had access to regular supervisions and development opportunities.

Good



Is the service caring?

The service was not always caring.

People's personal information was not stored securely.

People were supported by staff who were kind and caring.

People were involved in their care.

Requires Improvement



Is the service responsive?

Inadequate



The service was not responsive.

People's care records did not contain accurate, up to date information.

People were not always assessed to identify their needs and care plans did not detail how care needs would be met.

Where people had specific needs these were not being met. Deterioration in people's condition was not always identified and action was not taken as a result.

Is the service well-led?

The service was not well-led.

Actions required as a result of our previous inspection had not been completed.

Quality assurance systems were not effective as they had not identified the issues we found during this inspection.

Systems to enable the provider to seek feedback in order to monitor and improve the service had not been implemented. Inadequate •





Florence House

Detailed findings

Background to this inspection

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008, to look at the overall quality of the service, and to provide a rating for the service under the Care Act 2014.

This inspection took place on 10 and 11 February 2016. The inspection was carried out by three inspectors and an expert by experience (ExE). An expert-by-experience is a person who has personal experience of using or caring for someone who uses this type of care service.

Before the visit we looked at notifications we had received. Providers tell us about important events relating to the care they provide using a notification. This enabled us to ensure we were addressing potential areas of concern. The provider completed a Provider Information Return (PIR). This is a form that asks the provider to give some key information about the service, what the service does well and improvements they plan to make

During our inspection we spoke with 13 people who used the service and seven relatives and visitors. Not everyone we met was able to tell us their experiences, so we used the Short Observational Framework for Inspection (SOFI). SOFI is a specific way of observing care to help us understand the experience of people who could not talk with us.

We spoke with the registered manager, the provider, a nurse, the chef, the activity coordinator and six care staff. We looked at 7 people's care records, including records relating to medicines. We looked at a range of records about how the home was managed. We also spoke to the commissioners of the service.

During the inspection we spent time in the home and observed care practice and interactions between people and staff.

Requires Improvement

Is the service safe?

Our findings

At our comprehensive inspection on 22 and 29 May 2015 and our focused inspection on 17 August 2015 we found several concerns relating to the safety of people living in the service. This was a breach of Regulation 12 of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Following our August inspection the provider sent us an action plan telling us how they were going to meet their legal requirements.

In May and August 2015 we found that medicines were not being managed safely. At this inspection we found that improvements had been made. Medicines were managed safely and people received their medicines as prescribed. Medicine administration records (MAR) were printed and contained all information related to the administration of people's medicines. Systems were in place to monitor medicines and ensure people had access to their prescribed medicines and medicines that were 'as required' (PRN).

At our May and August 2015 inspections we found people were not protected from harm as staff were not clear about their responsibilities to identify and report concerns relating to abuse. At this inspection all staff we spoke with had received safeguarding training and were knowledgeable about the signs of different types of abuse. Staff told us they were confident to report any concerns and would report to the manager or to outside agencies if necessary. The service had systems in place to record and report all safeguarding concerns and these were used effectively.

At this inspection people's care records did not always include completed risk assessments. For example, one person's care record identified the person required two carers and a hoist to support them to move. There was no risk assessment identifying how this support need had been identified. The person's daily record stated, 'using stand aid, but said sling was hurting [person]. Nurse informed'. No moving and handling risk assessment had been completed on the person's admission to the service or following the concern. Another person's care plan stated the person had bed rails on their bed. There was no risk assessment identifying the risk to the person or indicating why bed rails were required.

Where risk assessments had identified a risk to the person, care plans were not always present to identify how the risk would be managed. For example, one person's care plan contained a risk assessment in relation to the risk of developing pressure ulcers. There was no care plan identifying what support was needed to minimise the risk of pressure damage.

This was a breach of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

People told us there were enough staff to meet their needs. One person said, "Staff are always checking on me". Throughout the inspection call bells were answered promptly and requests for support were responded to in a timely manner.

Staff told us staffing levels were sufficient to meet the needs of the people they supported. Comments included; "Yes I would say so, with the clients we have at the moment. But when dependency goes up, staffing levels don't always" and "Staffing is better, we have quite a few new starters (care staff)".

Since our last inspection the registered manager had implemented a dependency assessment tool. This enabled the registered manager to calculate the staffing levels required to meet people's needs. The dependency assessment for each person was reviewed monthly. We looked at the staffing rotas for a four week period and saw assessed staffing levels were achieved. The service covered any shortfalls in staffing levels by arranging staff from an agency. Staff told us regular agency staff were used to ensure they knew people well and were able to meet people's needs. However, as risk assessments did not always identify risks to people and how the risks would be managed we could not be sure the dependency assessments were accurate.

Staff files showed that relevant checks had been completed to ensure people were supported by staff who were suitable to work with vulnerable people. Checks included employment and character references, employment history and disclosure and barring checks (DBS). DBS checks enable employers to make safer recruitment decisions.



Is the service effective?

Our findings

At our comprehensive inspection on 22 and 29 May 2015 and our focused inspection on 17 August 2015 we found people were not being supported in line with the Mental Capacity Act 2005. The Mental Capacity Act 2005 (MCA) provides a legal framework for making particular decisions on behalf of people who may lack the mental capacity to do so for themselves. The Act requires that as far as possible people make their own decisions and are helped to do so when needed. When they lack mental capacity to take particular decisions, any made on their behalf must be in their best interests and as least restrictive as possible. This was a breach of Regulation 11 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. We also found staff did not always receive appropriate support and were not always knowledgeable about people's needs. This was a breach of Regulation 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Following our inspection in August 2015 the provider sent us an action plan telling us how they were going to meet their legal requirements. At this inspection we found the provider had met all the actions.

People's care plans contained mental capacity assessments relating to specific decisions. Where people were assessed as lacking capacity to make specific decisions best interest decisions had been made involving people who knew the person. For example, one person's care plan contained a capacity assessment in relation to their capacity to decide whether to remain living at Florence House. A best interest meeting had been held, involving health and social care professionals and the person's relative.

Staff had a clear understanding of the principles of the MCA and how to support people who may lack capacity to make certain decisions. One care worker told us, "I see it as being about when someone is able to make a decision for themselves; if they can't then it's about acting in their best interests. If you can you respect their wishes".

Since our inspection in August 2015 the registered manager had submitted appropriate deprivation of liberty (DoLS) applications to the supervisory body where people had been assessed as being deprived of their liberty. DoLS aim to make sure that people in care homes are looked after in a way that does not inappropriately restrict their freedom.

Staff we spoke with told us they felt supported in their role. Staff had received an annual appraisal and had regular one to one meetings with the registered manager. Comments included: "I have one to one meetings with [registered manager] about three times a year. It's the kind of work where you are talking all the time, you don't wait for a meeting" and "[Registered manager] does supervision every two months. But I don't need to wait for supervision if I have a problem".

The service had a training officer who monitored staff training to ensure staff had the skills and knowledge to meet people's needs. Staff told us they had received training which included mental capacity, fire safety, medicine management, food hygiene, infection control and safeguarding. Training was a combination of face to face and on line training. Staff had completed training in specific conditions which included epilepsy,

Parkinson's disease, dementia and diabetes.

Staff had access to development opportunities. Staff had achieved national qualifications at level two and three in social and health care.

Staff were knowledgeable out the needs of the people they supported. For example, we spoke to staff about a person who remained in bed. Staff were able to tell us about the support the person needed in relation to pressure relief and nutrition and hydration.

People were positive about the food and drink they received. One person said, "We always get a choice. I get all I want". People were able to eat in the lounge areas or in their own rooms. Where people chose to eat in their room food was served in a timely manner and staff sat with people and supported them where this was needed.

People were offered a choice of lunchtime meals in the morning. If people did not like the choices or they changed their mind an alternative was offered. For example, one person requested poached eggs on toast and this was provided.

Snacks and drinks were available throughout the day. One person requested a bacon sandwich during the morning and this was prepared for them.

Care plans showed people were supported to access health professionals including podiatrists and specialist nurse. People were seen regularly by their GP.

Requires Improvement

Is the service caring?

Our findings

At our inspection in May 2015 we found people's records were not stored safely to ensure personal information was kept confidential. At this inspection we found people's care records were still kept in the main office. The office door was open and easily accessible to visitors entering the home via the main entrance. When we arrived for the inspection we were able to enter the home and have direct access to people's records in the office. There were many occasions during the inspection when the office was not staffed and the door was open.

This was a breach of Regulation 17 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

People were positive about the caring nature of the staff. Comments included: "Staff are very good"; "The staff are very good and it's a lovely place" and "I'm well looked after".

Relatives were complimentary about the care staff. Comments included: "I think the staff are wonderful"; "Carers (care staff) are very nice" and "Staff are very kind and welcoming. They're nice to her, kind to her".

Relatives were positive about the supportive relationships they had with management and staff and told us they were involved in people's care. One relative told us, "I am very included in [person's] care. They are very welcoming and let me help, which is really important".

Staff spoke with people in a kind and caring manner. For example, we saw one person being supported into one of the communal lounges. Staff asked the person where they would like to sit; the person took some time to decide. The member of staff waited patiently, showing them the different chairs that were available. When the person had chosen they were supported to stand using their mobility aid. The member of staff explained what was going to happen and what the person needed to do to transfer. Throughout the interaction the member of staff was encouraging and supportive.

People were treated with dignity and respect. We saw that people were supported in a discreet manner by staff when they required help with personal care needs. For example, one person was supported to leave the communal area. The member of staff spoke quietly to the person explaining what was happening and why the person might like to go back to their room.

Throughout the day we saw many positive interactions. People and staff laughed and joked together.

The service supported people to remain at Florence House to the end of life if that was their wish. One person was being supported with end of life care at the time of our inspection. The person had an end of life care plan in place which included who the person wished to be present, the treatment the person would prefer and their spiritual needs. There was a care plan in place to ensure the person was kept free of pain. We saw the person was receiving regular pain relief to keep them comfortable. The person's relative told us they were happy with the care the person was receiving.

Another person who was nearing the end of their life had expressed a wish to go home. The service was supporting the person and their relative to achieve this.		



Is the service responsive?

Our findings

At our inspection in May 2015 we found that people's care plans did not always contain accurate, up to date information. This was a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Following our inspection in August 2015 the provider sent us an action plan telling us how they were going to meet their legal requirements.

However, we found at this inspection improvements had not been made. People's care records did not always contain accurate information. For example, one person's care record contained information that referred to a person with a different name and gender. We could not be sure which person the information related to. We found similar issues at our inspection in May 2015 and although this care record had been updated since our inspection in August 2015 it was still not accurate.

People's care plans did not always contain sufficient detail to identify how people's needs should be met. For example, one person's fluid intake was being monitored. The person's care plan stated 'provide adequate fluids'. We saw that fluid intake was being recorded but were unable to ascertain whether this was sufficient to meet the person's needs. Staff we spoke with were not aware how much fluid the person required.

People's care plans were not always up to date. For example, one person's care plan identified how the person should be supported to eat and drink. The person had become extremely unwell and no longer needed the support detailed in the care plan. The care plan had not been updated to reflect the changes.

Records were not always completed clearly to reflect the support people received. For example, one person required support to reposition every two hours when in bed. Records relating to the repositioning of the person were made on three different documents. It was not clear which document should be completed and we could not be sure the person had been repositioned in line with their care plan.

This was a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

People were not always fully assessed prior to accessing the service and care plans did not always contain details where needs had been identified. For example, one person had no completed assessments relating to moving and handling, malnutrition and falls. Another person's care plan contained an 'assessment of short term/initial care needs'. The assessment identified the person was 'immobile'. However there was no care plan detailing how the person should be supported to transfer. We could not be sure people's needs were being met.

People were not always receiving support to meet their needs. For example, one person's care plan identified they were at risk of developing pressure sores. The care plan stated the person should be provided

with a pressure relieving cushion when sitting out of bed. During our inspection we saw the person was sat in a wheelchair for six hours without a pressure cushion. We spoke to the registered manager who told us the person had become anxious when asked to transfer to an armchair and had been left in their wheelchair. The registered manager had not taken appropriate action to avoid the risk of this person developing pressure sores.

Care plans contained details of people who required thickened fluids due to the risk of choking. One person's care plan identified they required fluids to be thickened to 'stage 1', which meant one scoop of thickener in 100mls of fluid and two scoops of thickener in 200mls of fluid. The care plan relating to the consistency of fluid was dated 23 May 2014. There was no review of the information and no input from the Speech and Language Therapist. We spoke with staff about the person's fluid. Their comments included; "It depends on the drink, I just do it until it looks right" and "Three scoops in tea and two and a half in juice". We could not be sure people had received fluids of the correct consistency to meet their needs. We spoke to the registered manager who told us they would seek advice from health care professionals.

Records did not always indicate what action had been taken as a result of issues identified. For example, one person was identified as at high risk of pressure damage. The daily record for this person stated, 'Small break on coccyx. Marks on right hip. Looked at by nurse'. There was no record in the person's care plan of what had happened as a result of the examination by the nurse. We looked at the handover notes for the date entered on the daily record. The handover record stated, 'groins healed. Slight red buttocks' and 'groins getting better'. This meant we were unclear as to whether the person had skin damage and if so whether it was being properly managed. We spoke to the registered manager who stated the person did not have any pressure damage. However the registered manager advised us they would ask the nurse to examine the person to ensure they had no damage to their skin.

Where people were losing weight their condition was not monitored regularly and was not reflected in people's care plans. There was no record of action taken as a result of people's weight loss. For example, one person's care plan identified the person should be weighed monthly. The person's weight was recorded for three months since June 2015. Records showed the person had lost more than 15kg of weight. The person's Malnutrition Universal Screening Tool was reviewed on 8 June 2015 and had not been reviewed since to reflect the person's current weight. We asked the nurse how weight loss was monitored and they told us staff would report weight loss to the nurse or manager. There was no record that the person's weight loss had been noted and no record of any action being taken. We spoke to the registered manager who told us they would take action to review this person's weight.

During the first day of our inspection the activity coordinator was not on duty. People did not have access to any activities to interest them. Throughout the day people were watching television in their rooms or in the three communal areas of the home. Some people in their rooms sat for long periods of time without any social interaction. People in communal areas of the home spent long periods asleep. We spoke to the registered manager about how people accessed social activities when the activities coordinator was not on duty. The registered manager advised us care staff would engage people in activities during the afternoon when the home was "quieter". We did not see any activities taking place.

We spoke with staff about the activities in the home. Staff told us there was not time to engage people in activities. When speaking about activities one member of staff told us, "There's not enough". Another member of staff said social activities were "Slightly lacking".

We saw that some people's rooms were personalised. However rooms were not always tidy or homely. For example, we saw that one person's room had unused equipment on the floor, two wheelchairs were being

stored in the room that did not belong to the person, the bed was not made tidily and the person's pillow was held together with sticking tape. We spoke to the provider who arranged for the room to be tidied and a new pillow was provided for the person.

This was a breach of Regulation 9 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

On the second day of our inspection the activity coordinator was on duty. We saw many examples of group activities that had taken place in the home. The activity coordinator told us they visited people in their own rooms and spent time with them. The activity coordinator arranged for a local minister and priest to visit people in the home. The activity coordinator was knowledgeable about people's histories and was completing social activity information for people's care plans.

People told us they knew how to make a complaint and felt confident to do so. One relative told us, "I can talk to [registered manager] and [proprietor] at any time. They always sort things out quickly".

The home had a complaints policy and procedures in place. There were no recorded complaints since our inspection in May 2015. However one person's daily record stated, '[Person] complained that staff were being nasty to her'. We spoke to the registered manager and asked if they were aware of the concern. The registered manager told us they had spoken to the person who had said it was other residents being 'nasty to her'. The registered manager told us there had been no record made of this complaint and any action taken to resolve the concern. This meant the procedures had not been followed. We could not be sure the complaints system was effective.



Is the service well-led?

Our findings

At our inspection in March 2015 we found there were not effective systems in place to monitor and improve the quality of the service. This was a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Following our inspection in August 2015 the provider sent us an action plan telling us how they were going to meet their legal requirements. The action plan stated that actions would be completed by 1 October 2015.

At this inspection we found improvements had not been made. The provider action plan told us 'records will be audited to ensure accurate information is maintained on the people who use our service'. Although some care plans had been audited the issues we found during our inspection had not been identified through the audit system. This meant people's care records did not always accurately reflect their care needs.

The provider action plan stated that the service would carry out surveys to seek feedback on the quality of the service and that monthly meetings would be held with people using the service from September 2015. These actions had not been completed. People and their relatives told us they were not aware of any meetings and had not been asked for feedback on the service. There was no formal method of communication to enable people to know what was happening in the home or for people and their relatives to give feedback on the service. This meant the provider did not have effective systems in place to gain feedback on the service and use this information to improve the quality of the care.

A coded lock was to be fitted to the office door to ensure people's personal information was protected. The lock had been fitted. However the door to the office remained open throughout our inspection.

At this inspection we found the provider had not introduced effective systems to monitor the quality of the service. Although some audits were completed including; dignity, cleaning, care plans and maintenance there was no clear action taken as a result of issues found. For example, we spoke to the provider about issues identified by a cleaning audit. The providerr told us issues from the cleaning audit "Feed into the maintenance list". There was no system to ensure that issues identified had been addressed. The audits had not picked up issues found during this inspection. For example, the person's pillow that was held together by tape had not been reported or identified through the monitoring processes.

All accidents and incidents were recorded. The registered manager told us monthly audits were being carried out of accidents and incidents. However the audits file commenced from January 2016 and there was no audit completed for January 2016. The registered manager told us they had not had time to complete the January audit. There were no accident and incident audits available for 2015. This meant there were not effective systems in place to monitor accidents and incidents in order to identify trends and themes.

This was a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Although the management team were aware of the concerns relating to ineffective systems identified at the previous inspection in May 2015, there was a lack of recognition in relation to the impact of not having effective quality monitoring systems in place.

The registered manager told us they were aware of some of the issues we found during this inspection; however there was no action plan identifying what actions would be taken and a time scale identifying when actions would be completed. For example, the registered manager told us new care plan paperwork was being developed. They were unable to tell us when all the care plans would be reviewed and the new care plans completed.

The registered manager spent time supporting people and staff; however they were not always knowledgeable about people's needs and did not have correct knowledge relating to delivery of care. For example, the registered manager told us quantities of thickening agent used for people at risk of choking varied depending on whether the drink was hot or cold. This was not in line with guidance from speech and language therapists.

During our inspection it was not always clear who was responsible for managing the staff on duty. The nurse was busy doing medicines and other nursing tasks and had little time to guide and instruct staff relating to meeting people's needs. Staff were task focused and did not find time to spend with people other than when they were supporting people to meet their care needs. One member of staff told us they felt there needed to be more delegation of work in order to ensure shifts ran smoothly and tasks got completed.

Although we saw many kind and caring interactions throughout the inspection there were aspects that indicated the culture was task focused and not always centred on the needs of people using the service. The lack of personalisation and the unkempt appearance of some rooms indicated an acceptance of that standard of care. Staff did not take time to make the environment tidy and this was not identified and addressed by senior staff or the registered manager.

People, their relatives and staff were positive about the registered manager and the provider. Everyone told us they were approachable. During our inspection we saw relatives speaking with the registered manager and the provider. There were positive interactions where relatives were able to ask for information and advice. We saw the registered manager comforting a relative who was distressed. The registered manager showed kindness and compassion.

Staff told us they had regular staff meetings and were encouraged to make suggestions and raise any issues. Comments included: "You're able to have your say. It often turns into a good debate. People [staff] get their say" and "We're able to bring things up if needed". Records showed that the registered manager and proprietor had been open and transparent with staff following the CQC inspection.

This section is primarily information for the provider

Action we have told the provider to take

The table below shows where regulations were not being met and we have asked the provider to send us a report that says what action they are going to take. We did not take formal enforcement action at this stage. We will check that this action is taken by the provider.

Regulated activity	Regulation
Accommodation for persons who require nursing or personal care	Regulation 12 HSCA RA Regulations 2014 Safe care and treatment
Treatment of disease, disorder or injury	Care and treatment was not always provided in a safe way for service users. Risk assessments were not completed to identify risks to service users. Where risks were identified care plans were not in place to identify how risks would be managed. Regulation 12.