**NAME OF PROVIDER OR SUPPLIER**

EYE SURGERY CENTER OF NEW ALBANY, LLC  
520 W FIRST ST  
NEW ALBANY, IN 47150

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>REGULATORY OR LSC IDENTIFYING INFORMATION</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q 0000</td>
<td>Bldg. 00</td>
<td></td>
<td>This visit was for investigation of a federal ambulatory surgery center complaint.</td>
<td>Q 0000</td>
<td></td>
<td></td>
<td>Q 000 Acknowledge that Survey did in fact occur on 18 February 2020</td>
<td></td>
</tr>
<tr>
<td>Q 0082</td>
<td>Bldg. 00</td>
<td></td>
<td>Complaint Number: IN00316949 Substantiated: Deficiencies related to the allegations are cited. Date of Survey: 2/18/20 Facility Number: 005401 QA: 2/26/20 416.43(b), 416.43(c)(2), 416.43(c)(3) PROGRAM DATA; PROGRAM ACTIVITIES (b)(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (b)(2) The ASC must use the data collected to - (i) Monitor the effectiveness and safety of its services, and quality of its care. (ii) Identify opportunities that could lead to improvements and changes in its patient care. (c)(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (c)(3) The ASC must implement preventive strategies throughout the facility targeting</td>
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</table>

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
### Statement of Deficiencies and Plan of Correction

**Identification Number**: 15C0001020  
**State**: IN  
**County**: New Albany  
**Address**: 520 W First St  
**City**: New Albany  
**State**: IN  
**ZIP Code**: 47150

**Provider Name**: Eye Surgery Center of New Albany, LLC  
**Effective Date**: 02/18/2020

#### Findings include:

1. **Facility Document Review**:
   - Review of incident/unanticipated event reports from 7/1/19 to 12/31/19 indicated the facility had 2 similar incidents related to surgical product/device errors not caught during pre-operative set-up or checks: On 7/18/19 an incorrect IOL (Intraocular Lens) power was implanted in patient P11 and on 11/11/19 an expired lens was implanted in patient P9. Corrective Actions, as noted on the 11/11/19 report included the following:
     - RN (Registered Nurse) verifies the expiration date along with the scrub tech (technician).
     - The expiration date of the implant becomes part of the surgical time-out at the beginning of the procedure.
     - IOLs (intraocular lens) are checked for outdates monthly, not every three months and pulled from the consignment.
   - Additional Notes: 12/10/19 - Corrective Action Meeting held...related to new process... During hand-off and time-out, lens model, diopter and expiration

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<tr>
<th>ID</th>
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<th>Regulatory or LSC Identifying Information</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Deficiency)</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q 0082</td>
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<td>Governing Board met on 26 February 2020 to review data from the 4th quarter of 2019 and to make annual assignments and approvals for calendar year 2020. The Policy and Procedure manual was approved and included recommended updates to include: General Clinical 110.6 Addendum G added: &quot;Specific to Implant: IOL (Intra-ocular Lens) Manufacturer, Model, Diopter, Expiration Date and Target Axis if Indicated (Toric IOL). The Clinical Director presented this and other changes to the Governing Board for approval along with explaining the rationale for the changes. Adverse Incident Reporting Training is completed with all employees at least annually which was completed on 28 February 2020 by the Clinical Director. Governing Board reviews and acts upon the recommendations of the Medical Advisory Committee which doubles as the QAPI Committee to which Incidents are reported for the preceding quarter via the QAPI Dashboard prepared by the Administrator and Clinical Director. The unusual occurrences / incidents for the fourth quarter of 2019 were</td>
<td>02/28/2020</td>
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**Event ID**: H1LZ11  
**Facility ID**: 005401  
**Page of 16**
STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION
IDENTIFICATION NUMBER
15C0001020

MULTIPLE CONSTRUCTION
A. BUILDING
B. WING
00 00

DATE SURVEY COMPLETED
02/18/2020

NAME OF PROVIDER OR SUPPLIER
EYE SURGERY CENTER OF NEW ALBANY, LLC

STREET ADDRESS, CITY, STATE, ZIP CODE
520 W FIRST ST
NEW ALBANY, IN 47150

ID
PREFIX
TAG
SUMMARY STATEMENT OF DEFICIENCY
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

3. Interviews:

On 2/18/20, between approximately 1:15 PM and 1:30 PM, A1, Clinical Director, verified that the committee meetings did not include analysis of unanticipated events for effectiveness and safety of its services and quality of care; having reviewed and discussed the incidents noted above and the minutes lacked documentation of the committee having investigated and analyzed the frequency and causes of general categories of specific types of adverse/unanticipated events.

Medical Supplies are stored in various locations where room and environmental conditions allow. Supplies in each area (Pre-Op, Holding, OR Suites, Laser Suite, Sub Sterile Corridor, Supply Room) are checked for expirations during the first week of each month by an assigned employee. The Clinical Director makes these assignments when she completes the staffing schedule usually four to six weeks in advance. The expiration date is highlighted or a colored sticker is placed next to the expiration to signify close to expiration and use first if still in date. Any items found to be out of date are pulled by the employee and given to the Clinical Director who will direct the proper destruction of the item.

On 24 February 2020 the Clinical Director held an in-service with the clinical team and presented an article “Lessons Learned: Wrong IOL” followed by open discussion around the article and occurrence here including the changes to the protocol.

Adverse Incident Reporting training was completed by all employees as part of their annual education by 28 February.
events. At approximately 1:40 PM, A1 indicated that following the 7/18/19 lens error incident, physician MD4 sent an article related to IOL implant errors and requested it be shared with staff as education. A1 indicated he/she failed to share the information with staff.

On 2/18/20, between approximately 3:15 PM and 3:30 PM, A4, Infection Control Nurse, indicated that the incident with patient P4 was an unanticipated event and that no incident report was completed. This training was led by the Clinical Director who is responsible for clinical training during initial orientation and annually thereafter.

Findings include:

1. Review of the document titled "Patient's Statement of Rights and Responsibilities", updated 2015, indicated the following:

   A patient, patient representative or surrogate has the right to (not all inclusive):
   
   - Be treated with respect, consideration and dignity
   - Be given opportunity to participate in decisions involving their health care...
   - Receive care in a safe setting
   - Be provided, to the degree known, complete information concerning... evaluation, treatment...
   - Exercise rights and respect for personal

   Q 0232 Education regarding Patient Rights, especially reviewed the part regarding patients’ right to know about their treatment(s) and plan of care which includes anything that may not have gone as planned and the employee’s responsibilities, is ongoing by the Clinical Director with a completion deadline of 31 March 2020.
property and persons, including the right to... Be fully informed about a treatment or procedure...

2. Review of medical records indicated that on 11/11/19, patient P9 underwent cataract surgery with an IOL (intraocular lens) implant of the left eye. The OR (operating room)/intraoperative notes/Nurses Notes section; included a lens label which indicated the lens expiration date to be 08/31/2019. The physician's Operative Report, dated 11/11/19 also included a copy of the lens label which indicated the lens expiration date to be 08/31/2019. The MR lacked documentation of the patient having been made aware that an expired lens was implanted during surgery.

3. Review of facility incident/unanticipated event reports indicated that on 12/9/19, upon return of patient P9 for surgery on the second eye, implantation of the expired lens on 11/11/19 was discovered by the OR circulating nurse on duty, A4, and a report was completed. The facility lacked documentation of the patient having been provided information of the incident related to his/her treatment.

4. Review of the manufacturer package insert for the type of lens, L1, implanted in patient P4 indicated the following:

   DIRECTIONS FOR USE: Examine the label on the unopened package for model, power...and expiration date.

   EXPIRATION DATE: Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to L1 Laboratories.

5. On 2/18/20, between approximately 3:15 PM...
and 3:30 PM, A4, circulating nurse/Infection Control Nurse, indicated that the incident with patient P4 was an unanticipated event, but no incident report was completed on that date. A4 verified that patient P9 was not notified of the expired lens having been implanted on 11/11/19 and was not informed of the treatment incident.

416.51(b) INFECTION CONTROL PROGRAM

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

Based on document review and interview, the center failed to maintain an effective, ongoing program by failing to ensure implementation of infection control policies and procedures (P&P) in 1 facility.

Findings include:

1. P&P review:
The P&P titled "Initial and Annual Education", approved/reviewed 9/10/18, indicated annual education, for all employees, would include, but not limited to, infection control.
The P&P titled "Patient Infestation of Lice, Scabies, Bed Bugs and Other Vermin", approved/reviewed 9/10/18, indicated; Persons with suspected or known infestations of lice, scabies, bed bugs and other vermin will not be accepted as patients due to the inability to properly isolate these patients and the associated risk of spreading infestation to other patients, healthcare personnel, or increased risk of an
infestation to the center.

2. Review of personnel files lacked documentation of nursing staff members; N2, CST (Certified Surgical Technician); N3, RN (Registered Nurse); or A1, RN/Clinical Director, having had infection control education in 2019.

3. Review of the medical record for patient P4 indicated that on 12/16/19 at 1232 hours, the patient, whose personal belongings were noted in the pre-operative area, to have bed bugs, arrived to PACU (Post-Anesthesia Care Unit).

4. Interviews:
   On 2/18/20, at approximately 4:00 PM, LPN (Licensed Practical Nurse) N4, indicated that after patient P4 was brought back to the pre-operative (pre-op) area and prepared for surgery, someone from the sign-in area notified the staff (pre-op), that bed bugs were noted on the patient/patient belongings. N4 verified that the patient was processed through the surgery center on that date.

   On 2/18/20, at approximately 5:15 PM, A4, Clinical Director, verified that nursing personnel N2, N3 and A1 did not have documentation of having had annual infection control training in 2019.

   Director on 2 February 2020 as part of the annual employee education.

   The Policy, Infection Control 260, Patient Infestation reviewed with leadership from the affiliated surgeon offices (John-Kenyon Eye Centers & Bennett & Bloom Eye Centers) by the ASC Clinical Director on 5 & 9 March 2020. The ASC registration and Clinic surgery counselors were instructed to contact either the Infection Control Nurse, Clinical Director or Administrator if they suspect a patient has a vermin infestation when the patient is with them prior to admission to the ASC. An in-service was also held with the ASC clinical staff regarding how to follow the policy, specifically how to care for the patient and handle their belongings and clothing in such a manner as to maintain the patient’s dignity but also how to contain the possible exposure.

   Per policy any patient with an infestation of vermin is to be isolated and their scheduled procedure(s) will be cancelled until such time as they have been deemed clear of the vermin. The Clinical Director and Infection Control nurse facilitated the training with the ASC employees by 9 March 2020.
## STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

- **IDENTIFICATION NUMBER**: 15C0001020
- **DATE SURVEY COMPLETED**: 02/18/2020
- **PROVIDER/SupPLIER/CLIA DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES**

### NAME OF PROVIDER OR SUPPLIER
**EYE SURGERY CENTER OF NEW ALBANY, LLC**
- **STREET ADDRESS, CITY, STATE, ZIP CODE**: 520 W FIRST ST, NEW ALBANY, IN 47150

### SUMMARY STATEMENT OF DEFICIENCY

#### ID: S 0000
**PREFIX TAG**: Bldg. 00
**REGULATORY OR LSC IDENTIFYING INFORMATION**: This visit was for investigation of a state licensure hospital complaint.

- **ID**: S 0000
- **PREFIX TAG**: Bldg. 00
- **REGULATORY OR LSC IDENTIFYING INFORMATION**: This visit was for investigation of a state licensure hospital complaint.

#### ID: S 0166
**PREFIX TAG**: Bldg. 00
**REGULATORY OR LSC IDENTIFYING INFORMATION**: Based on document review and interview, the governing body (GB) failed to ensure written policy and procedure (P&P) for surgical time out was updated to reflect recommended protocol changes for 1 facility.

- **ID**: S 0166
- **PREFIX TAG**: Bldg. 00
- **REGULATORY OR LSC IDENTIFYING INFORMATION**: Based on document review and interview, the governing body (GB) failed to ensure written policy and procedure (P&P) for surgical time out was updated to reflect recommended protocol changes for 1 facility.

### PROVIDER'S PLAN OF CORRECTION

#### ID: S 0000
**PREFIX TAG**: Bldg. 00
**REGULATORY OR LSC IDENTIFYING INFORMATION**: This visit was for investigation of a state licensure hospital complaint.

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- **PREFIX TAG**: Bldg. 00
- **REGULATORY OR LSC IDENTIFYING INFORMATION**: This visit was for investigation of a state licensure hospital complaint.

#### ID: S 0166
**PREFIX TAG**: Bldg. 00
**REGULATORY OR LSC IDENTIFYING INFORMATION**: Based on document review and interview, the governing body (GB) failed to ensure written policy and procedure (P&P) for surgical time out was updated to reflect recommended protocol changes for 1 facility.

- **ID**: S 0166
- **PREFIX TAG**: Bldg. 00
- **REGULATORY OR LSC IDENTIFYING INFORMATION**: Based on document review and interview, the governing body (GB) failed to ensure written policy and procedure (P&P) for surgical time out was updated to reflect recommended protocol changes for 1 facility.

### CROSS-REFERENCED TO THE APPROPRIATE CODES

- **410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES**: 410 IAC 15-2.4-1 (c)(5) (I)
- **Policy and Procedure manual was approved and included recommended updates to include:**
  - **General Clinical 110.6 Addendum G added:** "Specific to Implant: IOL"
that on 12/9/19, an incident/event was documented with the following information:

On 12/9/19, it was noted that patient P9, had had an expired lens implanted on 11/11/19.

Corrective Actions:

RN (Registered Nurse) verifies the expiration date along with the scrub tech (technician).

The expiration date of the implant becomes part of the surgical time-out at the beginning of the procedure.

IOLs (intraocular lens) are checked for outdates monthly, not every three months and pulled from the consignment.

Additional Notes:

12/10/19 - Corrective Action Meeting held...related to new process... During hand-off and time-out, lens model, diopter and expiration will be announced and verified.

2. Review of the P&P titled "Universal Protocol for Correct Identification of Patient, Procedure and Site", indicated it was most recently approved/reviewed 9/10/18. The P&P lacked documentation of the new time-out process.

3. On 2/18/20 at approximately 1:15 PM, A1, Clinical Director, verified that the center had not updated the Universal Protocol for Correct Identification of Patient, Procedure and Site (Time-out) P&P to reflect the recommended protocol changes to avoid occurrences similar to that identified in the 12/9/19 event report.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

IDENTIFICATION NUMBER
15C0001020

A. BUILDING 00
B. WING

ID
PREFIX
TAG

SUMMARY STATEMENT OF DEFICIENCY
(Each deficiency must be preceded by full regulatory or LSC identifying information)

ID
PREFIX
TAG

PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

COMPLETION DATE

EYE SURGERY CENTER OF NEW ALBANY, LLC
520 W FIRST ST
NEW ALBANY, IN 47150

NAME OF PROVIDER OR SUPPLIER
STREET ADDRESS, CITY, STATE, ZIP CODE

S 0414
410 IAC 15-2.5-1
INFECTION CONTROL PROGRAM
410 IAC 15-2.5-1(f)(1)

(f) The center shall establish a committee to monitor and guide the

each month by an assigned employee. The Clinical Director makes these assignments when she completes the staffing schedule usually four to six weeks in advance. The expiration date is highlighted or a colored sticker is placed next to the expiration to signify close to expiration and use first if still in date. Any items found to be out of date are pulled by the employee and given to the Clinical Director who will direct the proper destruction of the item.

On 24 February 2020 the Clinical Director held an in-service with the clinical team and presented an article "Lessons Learned: Wrong IOL" followed by open discussion around the article and occurrence here including the changes to the protocol.

Adverse Incident Reporting training was completed by all employees as part of their annual education by 28 February 2020. This training was led by the Clinical Director who is responsible for clinical training during initial orientation and annually thereafter.
## Infection Control Program

The Infection Control Committee shall be a center or medical staff committee that meets at least quarterly with membership that includes, but is not limited to, the following:

1. The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).
2. A representative from the medical staff.
3. A representative from the nursing staff.
4. Consultants from other appropriate services within the center as needed.

Based on document review and interview, the center failed to ensure that the infection control committee met at least quarterly during the 4 quarters of 2019.

Findings include:

1. Review of 2019 infection control meeting minutes; 1 (one) typed document titled "First & Second Quarter Infection Control Meeting", dated 6/6/2019; and 1 hand written paper with the heading "Oct Meeting Topics", no date indicated, lacked documentation of the infection control committee having met at least quarterly during 2019.
2. On 2/18/20, between approximately 3:15 PM and 3:30 PM, in interview, A4, Infection Control

### New Albany, IN 47150

15C0001020 02/18/2020

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**DATE SURVEY COMPLETED**

**NAME OF PROVIDER OR SUPPLIER**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

**ID**

**PREFIX**

**TAG**

**ID**

**PREFIX**

**TAG**

**COMPLETION DATE**

**Provider's Plan of Correction**

(Each corrective action should be cross-referenced to the appropriate deficiency)

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**Event ID:** H1LZ11  **Facility ID:** 005401  **If continuation sheet**
<table>
<thead>
<tr>
<th>ID</th>
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<th>Summary Statement of Deficiency</th>
<th>(Each Deficiency Must Be Preceded By Full Regulatory Or LSC Identifying Information)</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>S 0930</td>
<td>Bldg. 00</td>
<td>410 IAC 15-2.5-5 PATIENT CARE SERVICES</td>
<td>410 IAC 15-2.5-5(b)(5)</td>
<td>Nurse, indicated the center had 2 (two) infection control committee meetings in 2019, A4 also indicated that the hand written notes provided were his/her documentation of an infection control meeting that took place in October of 2019 and that no other meetings occurred during that year.</td>
<td>02/28/2020</td>
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</tbody>
</table>

Findings include:

1. Review of the policy titled "Initial and Annual Education", approved/reviewed 9/10/18, indicated annual education, for all employees, would include, but not limited to, infection control.
2. Review of personnel files lacked documentation of nursing staff members; S2, CST (Certified Surgical Technician); N3, RN (Registered Nurse); or A1, RN/Clinical Director, having had infection control education in 2019.

The Infection Control Nurse will set formal quarterly meetings for the IC Committee and keep typed minutes from each meeting rather formal or informal. The first quarter 2020 meeting will be held by 31 March 2020.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**Identification Number**: 15C0001020  
**Multiple Construction**  
**Date Survey Completed**: 02/18/2020

**Address**: 520 W First St, New Albany, IN 47150

**Provider/Supplier Information**

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<td>Bldg. 00</td>
<td></td>
<td>PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</td>
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</tbody>
</table>

**Summary Statement of Deficiency**

3. On 2/18/20, at approximately 5:15 PM, A4, Clinical Director, verified that nursing personnel N2, N3 and A1 did not have documentation of having had annual infection control training in 2019.

410 IAC 15-2.5-7

**Provider’s Plan of Correction**

(c) A safety management program must include, but not be limited to, the following:

1. Review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.

Based on document review and interview, the center failed to ensure that the safety management committee included review of safety functions for analysis of unanticipated events in 1 facility within the last 2 quarters of 2019.

Findings include:

1. Review of facility safety/risk policies and procedures (P&P), all approved/reviewed 9/10/18, indicated the following:

The P&P titled "Patient Safety Program":

- The patient safety program integrates risk management, performance improvement, and a review of processes, functions, and services to improved safety by reducing the risk of system or process failures.

- By establishing a system...to encourage the reporting of unanticipated events, the

**Compliance Date**

S 1180 Governing Board reviews and acts upon the recommendations of the Medical Advisory Committee which doubles as the QAPI Committee to which Incidents are reported for the preceding quarter via the QAPI Dashboard prepared by the Administrator and Clinical Director. The unusual occurrences / incidents for the fourth quarter of 2019 were presented at the February 26 Board Meeting by the Clinical Director.

Adverse Incident Reporting Training is completed with all employees at least annually which was completed on 28 February 02/28/2020
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

IDENTIFICATION NUMBER
15C0001020

DATE SURVEY COMPLETED
02/18/2020

PROVIDER/SUPPLIER/CLIA
MULTIPLE CONSTRUCTION
A. BUILDING
00
B. WING

NAME OF PROVIDER OR SUPPLIER
EYE SURGERY CENTER OF NEW ALBANY, LLC
STREET ADDRESS, CITY, STATE, ZIP CODE
520 W FIRST ST
NEW ALBANY, IN 47150

NAME OF PROVIDER OR SUPPLIER
EYE SURGERY CENTER OF NEW ALBANY, LLC
STREET ADDRESS, CITY, STATE, ZIP CODE
520 W FIRST ST
NEW ALBANY, IN 47150

organization can review...

Data analysis of unanticipated events will be used to identify and implement changes that will improve the quality of care, treatment, and services...

The patient safety committee will...review and evaluate the quality of safety measures used in the organization to assist with implementation of the safety activities. This committee can be the same members as the quality improvement/performance improvement committee...reviewing all areas of performance, safe work environment, and safe patient care processes.

The P&P titled "Risk Management/Patient Safety Officer Assignments":

The staff reports all incidents and completes the incident report form appropriately, and...

The P&P titled "Risk Management and Patient Safety Policy Statement":

To assure...quality health care, the organization has established a risk management and patient safety program to minimize adverse events.

Risk management and patient safety activities include:

The investigation and analysis of the frequency and causes of general categories and specific types of adverse and unanticipated events...

The P&P titled "Management Responsibilities":

Safety and risk management activities should be discussed at staff and committee meetings throughout the year.

2. Facility document review:

Review of incident/unanticipated event

2020 by the Clinical Director.

Included in the training was a discussion regarding what situations warranted an Incident Report.
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EYE SURGERY CENTER OF NEW ALBANY, LLC

**STREET ADDRESS, CITY, STATE, ZIP CODE**

520 W FIRST ST
NEW ALBANY, IN 47150

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**SUMMARY STATEMENT OF DEFICIENCIES**

Reports from 7/1/19 to 12/31/19 indicated the facility had 2 similar incidents related to surgical product/device errors not caught during pre-operative set-up or checks: On 7/18/19 an incorrect IOL (intraocular lens) power was implanted in patient P11 and on 11/11/19 an expired lens was implanted in patient P9.

Review of medical records indicated that on 12/16/19, patient P4 was noted and reported to be infested with a parasite. On that date, the patient underwent cataract surgery with an intraocular lens implant. The facility lacked documentation of an incident/unanticipated event having been completed.

Review of safety committee meeting minutes dated 9/23/19, titled "Third Quarter", and those titled "Fourth Quarter" without a date, lacked documentation of the committee having analyzed data from unanticipated events, having reviewed and/or discussed incidents and the minutes lacked documentation of the committee having investigated and analyzed the frequency and causes of general categories of specific types of adverse/unanticipated events.

Review of quality assurance performance improvement (QAPI) committee meeting minutes, dated 5/15/19, titled "First and Second Quarter", and those dated 12/28/19, titled "Fourth Quarter", lacked documentation of the committee having analyzed data from unanticipated events, having reviewed and/or discussed incidents and the minutes lacked documentation of the committee having investigated and analyzed the frequency and causes of general categories of specific types of adverse/unanticipated events.

3. On 2/18/20, between approximately 1:15 PM...
and 1:30 PM, A1, Clinical Director, verified that the safety committee meetings did not include analysis of unanticipated events, discussion of incidents or evaluation of like causes of events. On 2/18/20, between approximately 3:15 PM and 3:30 PM, A4, Infection Control Nurse, indicated that the incident with patient P4 was an unanticipated event and that no incident report was completed.