

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL  
SOUTHERN ZONE, CHENNAI**

**Original Application No. 123 of 2017 (SZ)**

**IN THE MATTER OF:**

Dr. Krithika Gokulnath

.....Applicant

Versus

Registrar, Anna University and 8 Ors

.....Respondent(s)

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**Place: Chennai  
Date: 16.02.2021**

*H.D. Varalaxmi*

**DEPONENT**

**H.D. VARALAXMI, M.Tech**  
Regional Director  
CENTRAL POLLUTION CONTROL BOARD  
(MoEF & CC. Govt. of India)  
Regional Directorate (Chennai)  
2nd Floor, 77-A, South Avenue Road,  
Arumbatur Industrial Estate, Chennai - 600 058



**BEFORE THE NATIONAL GREEN TRIBUNAL (SOUTHERN ZONE) CHENNAI**

**ORIGINAL APPLICATION NO. 123 OF 2017**

**IN THE MATTER OF:**

**Dr. KRITHIKA GOKULNATH**

**.....APPLICANT**

**Versus**

**REGISTRAR, ANNA UNIVERISITY AND 8 ORS**

**.....RESPONDENT(S)**

**ACTION TAKEN REPORT FILED ON BEHALF OF 4<sup>TH</sup> RESPONDENT CENTRAL POLLUTION CONTROL BOARD (CPCB) WITH REGARD TO HON'BLE TRIBUNAL ORDER DATED NOVEMBER 18, 2020**

I, H. D. Varalaxmi, D/o Shri H.S. Devaiah, Hindu, aged about 51 years and having office at the Regional Directorate – Chennai, Central Pollution Control Board, 2<sup>nd</sup> Floor, 77-A, Ambattur Industrial Estate, Chennai – 600 058, do hereby solemnly affirm and sincerely state as follows:

2. That I am presently working as Regional Director, Regional Directorate - Chennai, Central Pollution Control Board (hereafter called as CPCB), and have been authorized to file the action taken report of CPCB. I am fully conversant with the facts of the case and hence, competent and authorized to depose and swear the present report as under:
3. That the Hon'ble National Green Tribunal (Southern Zone), Chennai in Application No. 123 of 2017 order dated November 18, 2020 directed CPCB, to submit a further action taken report on the basis of the observations and conclusions on inspection of these institutions. Accordingly CPCB verified the present status of compliance by the institutions during January 20-21, 2021. The action taken report of the CPCB is enclosed as **Appendix**.

*H.D. Varalaxmi*

**DEPONENT**

**H.D. VARALAXMI, M.Tech**  
Regional Director  
CENTRAL POLLUTION CONTROL BOARD  
(MoEF & CC. Govt. of India)  
Regional Directorate (Chennai)  
2nd Floor, 77-A, South Avenue Road,  
Ambattur Industrial Estate, Chennai - 600 058

**VERIFICATION**

It is submitted that the Action Taken Report of CPCB is prepared based on field investigations carried out by an official of CPCB RD-Chennai. It is verified that the contents of the report are true and correct. Nothing has been concealed therein.

Signed and verified on this 16<sup>th</sup> day of February 2021 at Chennai

*H.D. Varalaxmi*

**DEPONENT**

**H.D. VARALAXMI, M.Tech**  
Regional Director  
CENTRAL POLLUTION CONTROL BOARD  
(MoEF & CC. Govt. of India)  
Regional Directorate (Chennai)  
2nd Floor, 77-A, South Avenue Road,  
Ambattur Industrial Estate, Chennai - 600 058

**COUNSEL FOR**

**4<sup>th</sup> RESPONDENT**



**APPENDIX**

**Action Taken Report of CPCB on**

**Dr. Krithika Gokulnath**

**Vs**

**Registrar, Anna University and 8 Ors**

**In**

**Original Application No.123 of 2017**

**Submitted to**

**Before the National Green Tribunal  
South Zone, Chennai**



**Central Pollution Control Board  
Regional Directorate, Chennai  
February 16, 2021**

**ACTION TAKEN REPORT OF CENTRAL POLLUTION CONTROL BOARD (CPCB)  
AS PER THE DIRECTION OF HONOURABLE NGT (SOUTH ZONE) ORDER DATED  
NOVEMBER 18, 2020 IN THE CASE OF O. A. NO. 123 OF 2017 TITLED: KRITHIKA  
GOKULNATH Vs. REGISTRAR, ANNA UNIVERSITY AND 8 ORS.**

## 1.0 Preamble

As per the directions of the Hon’ble NGT, Southern Bench, Chennai order dated July 7, 2020 in the matter of Original Application No. 123/2017 (SZ) Regional Office - Chennai inspected Anna and Pondicherry universities in respect of the implementation of Bio Medial Waste Management Rules, 2016 and also the guidelines issued by the Ministry of Science & Technology, Department of Bio-technology regarding scientific disposal of bio medical waste generated in Research/Educational Institutions dealing with DNA analysis. The independent inspection report was filed to NGT (SZ) on November 16, 2020. The case was heard on November 18, 2020 and Hon’ble NGT passed an order and the operative portion of the order is reproduced as under and the copy of the NGT order is annexed as **Annexure 1**:

*“..... The Tamil Nadu Pollution Control Board (TNPCB), Puducherry Pollution Control Committee as well as the Central Pollution Control Board (CPCB) are directed to submit a further action taken report on the basis of the observations and conclusions arrived at by them on inspection of these institutions by applying the principle of natural justice by giving an opportunity to the parties before imposing any penal action including imposition of environmental compensation against them....”*

## 2.0 Inspection of Universities

Before initiating action against the Anna & Pondicherry Universities, CPCB decided to inspect the universities and verify the present status of compliance w.r.t recommendations made by CPCB in earlier inspection. In this regard Bio-technology department of Anna University & Pondicherry University were inspected during January 20-21, 2021 respectively and verified the present status.

### 2.1 Anna University

On the day of inspection (January 20, 2021) the biotechnology department at Taramani campus was not fully operational, a few faculties & research scholars were present. The classes for UG & PG students are conducted through online. There were very few scholars present in the laboratories doing experiments. The table 1 below depicts compliance status:



**Table 1: Compliance status of Anna University**

<b>S. No.</b>	<b>Recommendations</b>	<b>Compliance status</b>
i.	<p>Anna university has obtained one time authorisation from TNPCB for the M/s SPIC BIOPROCESS LABORATORY, Taramani Campus, Chennai. The university has to identify the departments generating the Bio Medical Waste and authorisation has to be obtained. While obtaining the authorisation, the universities have to identify the category of waste generated from each department and clearly mention in the application.</p> <p>In case of M/s SPIC BIOPROCESS LABORATORY, authorisation is issued only for the yellow category of waste, whereas the red, yellow, blue and white category of waste is disposed to the M/s G. J. Multiclave Pvt. Ltd., TNPCB may once again review the category of waste generated by Anna university as per the schedule I of the BWM Rules, 2016 and accordingly authorisation may be issued.</p>	<p><b>Complied</b></p> <p>Tamil Nadu Pollution Control Board (TNPCB) as revised the authorisation for different category of waste as per the schedule I of the BWM Rules, 2016 and issued to Anna University on January 5, 2021. The copy of the revised authorisation is enclosed as <b>Annexure A.</b></p>
ii.	<p>The universities generating the BMW have to install a small weighing machine to quantify the waste generated from each laboratory/departments and recorded. So that the exact quantity of BMW generated, treated &amp; disposed shall be submitted to SPCBs/PCCs in the Annual report.</p>	<p><b>Complied</b></p> <p>Biotechnology department, Anna University has installed a small electronic weighing machine in the storage room for quantification of waste generated.</p>
iii.	<p>The universities have to maintain log book/ records for the segregation, collection, treatment and disposal of BMW. The records maintained should be made available for the monitoring team.</p> 	<p><b>Complied</b></p> <p>The Biotechnology department has maintained separate log books/records for collection, pretreatment, validation test for autoclave and disposal of BMW. The same was verified during inspection. The copy of the log book is attached as <b>Annexure B.</b></p>
iv.	<p>Treatment of BMW through autoclave should be followed according to the schedule II of the BWM, Rules 2016. The validation test should be</p>	<p><b>Complied</b></p> <p>The disinfection of Bio-medical waste through</p>

	done every week to ensure that the waste is disinfected effectively and as per the methods mentioned in schedule II of the BWM, Rules 2016.	autoclave is carried out according to the schedule II of the BMW Rules, 2016.
v.	The universities shall identify one dedicated person responsible for segregation, collection, treatment and disposal of BMW. The concerned person responsible should be trained accordingly to manage & handle the BMW efficiently.	<b>Complied</b> A dedicated person has been identified for segregation, collection, treatment & disposal of BMW. The concerned person has been imparted training to handle BMW.
vi.	As per the Bio Medical Waste Management Rules, 2016, it is mandatory that all the employees, staff and students need to be trained to handle & manage the BWM.	<b>Complied</b> The employees, staff & research scholars are aware of segregation and collection of waste in separate colour coded bins. The poster for disposing different category of waste was displayed in all the departmental laboratories.
vii.	A designated central storage room shall be identified within the premises for storage of bio-medical waste, till the waste is treated and disposed to Common Biomedical Waste Treatment Facility. The room should under the responsibility of a designated person and should be under lock & key.	<b>Complied</b> A designated central storage room has been identified and the waste is pre-treated and stored until collected by M/s M. J. Multiclave (India) Pvt. Ltd. On the day of inspection, eight bags of red and yellow category of waste were disposed. The copy of the manifest is attached in <b>Annexure B</b> .

Bio-technology department of Anna University is complying with all the recommendations of CPCB.





*BMW storage room under lock and key with all the facilities*

**2.2 Pondicherry University**

On the day of inspection (January 21, 2021), the university was not fully operational, only the Head of Departments with few faculties and research scholars were present. The admission for the next academic year was in progress. There were no activities in the research /experimental laboratories; few scholars/students were engaged in either paper publications or thesis writing in the computer labs. The faculties were conducting classes through online for UG & PG students. The table 2 depicts the compliance status:

**Table 2: Compliance status of Pondicherry University**

S. No.	Recommendations	Compliance status
i.	The universities generating the BMW have to install a small weighing machine to quantify the waste generated from each laboratory/departments and recorded. So that the exact quantity of BMW generated, treated & disposed shall be submitted to SPCBs/PCCs in the Annual report.	<b>Complied</b> Pondicherry University has installed a small electronic weighing machine for quantification of waste generated.
ii.	The universities have to maintain log book/ records for the segregation, collection, treatment and disposal of BMW. The records maintained should be made available for the monitoring team. 	<b>Complied</b> The Biotechnology department has maintained separate log books/records for collection, pretreatment, validation test for autoclave and disposal of BMW.
iii.	Treatment of BMW through autoclave should be followed according to the schedule II of the	<b>Complied</b> It was informed that

	BWM, Rules 2016. The validation test should be done every week to ensure that the waste is disinfected effectively and as per the methods mentioned in schedule II of the BWM, Rules 2016.	disinfection of Bio-medical waste through autoclave is carried out according to the schedule II of the BMW Rules, 2016. The spore test for the validation of autoclave is not carried out as it was informed that there was no generation of BMW and no log book is maintained.
iv.	The universities shall identify one dedicated person responsible for segregation, collection, treatment and disposal of BMW. The concerned person responsible should be trained accordingly to manage & handle the BMW efficiently.	<b>Complied</b> A dedicated person has been identified for segregation, collection, treatment & disposal of BMW. The concerned person has been imparted training to handle BMW.
v.	As per the Bio Medical Waste Management Rules, 2016, it is mandatory that all the employees, staff and students need to be trained to handle & manage the BWM.	<b>Complied</b> The employees, staff & research scholars are aware of segregation and collection of waste in separate colour coded bins. The poster for disposing different category of waste was displayed in all the departmental laboratories.
vi.	A designated central storage room shall be identified within the premises for storage of bio-medical waste, till the waste is treated and disposed to Common Biomedical Waste Treatment Facility. The room should under the responsibility of a designated person and should be under lock & key.	<b>Partial Complied</b> A construction of designated central storage room is under progress.
vii.	Pondicherry University to stop using the deep burial pit for disposing the BMW and sent the treated waste to the CBMTF as per the authorization. 	<b>Complied</b> The deep burial pit is closed and has a MoU with M/s Pondicherry Solid Waste Management Company Pvt. Ltd., but till now waste is not disposed to them.



Pondicherry University is complying with all recommendations except one recommendation which is partially complied due to construction of central storage room work under progress.

### 3.0 Action taken by CPCB

The Biotechnology department of Anna University was found complying with recommendations of CPCB, hence a letter was issued to University asking it to ensure continuance of compliance and to inform CPCB after resuming full operation so that CPCB may re-assess ground realities and compliance to bio-medical waste management rules, 2016. The copy of the letter addressed to Anna University is enclosed as *Annexure 2*.

The Pondicherry University was complying with recommendations of CPCB except for construction of central storage room which was partially completed, hence a letter was issued to University to ensure completion of storage room and to ensure continuance of compliance. Further, University was also requested to inform CPCB after resuming full operation so as to assess ground realities and compliance to bio-medical waste management rules, 2016. The copy of the letter addressed to Pondicherry University is attached as *Annexure 3*.

*Poornima*

**Smt. Poornima B M**  
**Scientist D**  
**Central Pollution Control Board**  
**Regional Directorate - Chennai**



**Item No.03:**

BEFORE THE NATIONAL GREEN TRIBUNAL  
SOUTHERN ZONE, CHENNAI

**Original Application No. 123 of 2017 (SZ)**

(Through Video Conference)

IN THE MATTER OF:

Dr. Krithika Gokulnath  
E 4503, E Block  
SNN Raj Serenity Apartments  
Begur Road, Elanahalli  
Bangalore – 560 068.

...Applicant(s)

**With**

Registrar,  
Anna University,  
Guindy, Chennai and Ors.

...Respondent(s)

**Date of hearing: 18.11.2020.**

**CORAM:**

**HON'BLE MR. JUSTICE K. RAMAKRISHNAN, JUDICIAL MEMBER**

**HON'BLE MR. SAIBAL DASGUPTA, EXPERT MEMBER**

For Applicant(s): Sri. Kaushik N Sharma

For Respondent(s): Smt. D. Latha for R1.  
Smt. Hema Srinivasan for R2.  
Sri. C. Kasirajan through  
M/s. Meena for R3.  
Smt. Jayalakshmi for R4.  
Sri. Ramachandra Moorthy for R6 & R7.  
Sri. S.N. Parthasarathi through  
M/s. Girija for R8.  
Smt. Sathyabama for R9.

## ORDER

1. The grievance in this application is regarding the disposal of the biomedical waste in an unscientific manner generated in DNA research units by the laboratories and research institutes without complying with the Biomedical Waste Management Rules, 2016.
2. As per order dated 20.03.2020, this Tribunal had considered the pleadings and passed the following order:

*“4. It is mentioned in the report that four research institutes were identified as generator of Biomedical Waste as per Rule 3 (e) of Bio-Medical Waste Management Rules, 2016 namely (i) Puducherry University, (ii) Vector Control Research Centre, (iii) Rajiv Gandhi Institute of Veterinary Education and Research, (iv) Pondicherry Bio-Tech Pvt. Ltd., Pillaichavady, Puducherry and the above research institutes were directed under Section 5 of Environment (Protection) Act, 1986 vide Letter dated 08.06.2017 to ensure proper collection, segregation, transportation and disposal of Bio-Medical Waste through Common Bio-Medical Waste Treatment Facility located at Thuthipet, Puducherry.*

*5. It is also mentioned in the report that except Pondicherry University, all other Research Centres have entered into an agreement with Common Bio-Medical Waste Treatment Facility for final disposal of their Bio-Medical Waste originated from their research activity through incineration process.*

*6. Pondicherry University was inspected on 24.02.2020 and noticed that laboratory waste generated from Bio-technology Department are autoclaved and disposed of through deep burial.*

*7. Show cause notice has been issued to them to apply for authorization to Puducherry Pollution Control Committee within three days after entering into an agreement with Bio-Medical Waste Treatment Facility.*

*8. They have already applied for authorization along with agreement with Common Bio-Medical Treatment Facility. Though a notice has been issued to Pondicherry University under Section 5 of Environment (Protection) Act, 1986 for non-complying with the*

provisions of the rules, there is nothing mentioned in the report as to whether any environment compensation has been imposed against the said university for non-complying with the Rules and for the past violation. If any application for authorization is pending then the Puducherry Pollution Control Committee is expected to dispose of that application as early as possible as without authorization the university is not expected to conduct the laboratory activities, though they have entered into an agreement with the Common Bio-Medical Waste disposal facility.

9. The Puducherry Pollution Control Committee is directed to submit a further report in this regard.

10. As regards, the first respondent/Anna University is concerned, learned counsel appearing for the Pollution Control Board submitted that inspection was conducted and they have got all necessary authorization and arrangements for disposal of the same with the Common Bio-Medical Waste Management treatment facility as provided under the Rules and they wanted to file a report to that effect.

11. Applicant who is present in court and who is a research scholar submitted that there are certain guidelines provided in the year 1990 as to how the genes collected for conducting DNA test have to be disposed of and also the applicant submitted that most of the guidelines have now become out dated and further study needs to be conducted in this regard in a scientific manner so that revised guidelines can be issued.

12. It is seen from the documents produced by the applicant herself that department of Bio-Technology, Ministry of Science and Technology, Government of India is the authority who is dealing with the issue and it is on the basis of the recommendations given by them that such things are being dealt with by institutions/laboratories dealing with such matter.

13. It is seen from the guidelines that Bio-Waste resulting from the laboratory experiments, industrial operation should be properly treated, so organisms are either destroyed or rendered harmless before disposal into the environment.

14. It is not known as to whether any further guidelines have been given as to how such organism are to be destroyed or made harmless before disposal into the environment and also whether there is any specific scientific method prescribed for such destruction by the Department of Bio technology in this regard.

15. So under such circumstances, we feel it appropriate to direct the sixth respondent to submit a detailed status report as to whether any further guidelines have been given to laboratories who are dealing with the DNA recombinant technology as to how the genes

collected have to be destroyed and made harmless before it was discharged into the environment and whether such guidelines have been properly adopted by the laboratories and if there is any violation who is the authority to take action against such lapse for non-compliance of the directions issued by the department in this regard.

16. The Registry is directed to communicate this order to the sixth respondent as well as the counsel appearing for the sixth respondent namely Sri. Karthikeyan, presently Assistant Solicitor General of India who represents the Central Government in this matter, so as to enable the department to file the report to this Tribunal and on that basis, necessary directions can be given by this Tribunal to the laboratory and the Pollution Control Board to implement the same in its letter and spirit.

17. The department is directed to submit the report to this Tribunal within a period of two months through e-mail at [ngtszfiling@gmail.com](mailto:ngtszfiling@gmail.com) or by e-filing.

18. In the meantime, the applicant is also directed to give her suggestions or best practices and deficiency if any, in the guidelines issued in the year 1990 and further improvement if any, to be done in this regard, so that the feasibility of that also can be directed to be considered by the department of Bio-technology to enable them to come with future action plan before the next hearing date.”

3. Thereafter, it was taken up on 07.07.2020 and passed the following order:-

“7. We have also received suggestions on best practices of handling and management of bio-medical waste generated from Educational/Research Institutions filed by the applicant through e-mail.

8. The applicant is directed to serve the copy of the same to the counsel for the respondents including the counsel appearing for the 6<sup>th</sup> respondent. 9<sup>th</sup> respondent wanted some more time to file the further report as directed by this Tribunal.

9. We direct the Regional Office, Central Pollution Control Board, Chennai to inspect the institutions mentioned in the application and submit an independent inspection and action taken report in respect of compliance/ violations committed by the institutions in respect of the implementation of Bio Medial Waste Management Rules, 2016 and also the guidelines issued by the 6<sup>th</sup> respondent department regarding scientific disposal of bio medical waste generated in Research/Educational Institutions dealing with

*DNA analysis. If there is any deficiency found, they are directed to take action against that person in accordance with law in consultation with the respective State Pollution Control Board and also the Pollution Control Committee.*

*10. The Regional Office, Central Pollution Control Board is also directed to consider the feasibility of implementing the suggestions of best practices submitted by the applicant to this Tribunal and submit their views on the same to this Tribunal.*

*11. The counsel for the applicant is directed to serve a copy of the suggestions of best practices submitted before this Tribunal to the officer of in charge of the Regional Office, Central Pollution Control Board, Chennai, so as to enable them to consider the same and submit the report on the same.*

*12. Two months time is granted to the committee and the authorities mentioned above to submit the report and also complying with the directions of this Tribunal in the earlier orders mentioned to this order and they are directed to submit the respective reports to this Tribunal on or before 15.09.2020 through e-mail @ [nqtszfiling@gmail.com](mailto:nqtszfiling@gmail.com) or by e-filing to this Tribunal.”*

4. The case was posted to 15.09.2020 for consideration of report and on 15.09.2020, it was adjourned to today by notification for that purpose.
5. When the matter came up for hearing to today through Video Conference, Sri. Kaushik N Sharma represented the applicant. Smt. D. Latha represented 1<sup>st</sup> respondent, Sri. C. Kasirajan through M/s. Meena represented 3<sup>rd</sup> respondent, Smt. Jayalakshmi represented 4<sup>th</sup> respondent, Sri. S.N. Parthasarathi through M/s. Girija represented 8<sup>th</sup> respondent, Smt. Sathyabama represented 9<sup>th</sup> respondent, Sri. Ramachandra Moorthy, Senior Panel Counsel for Central Government

represented respondents 6 & 7 and Smt. Hema Srinivasan proposed to appear for 2<sup>nd</sup> respondent.

6. We have received a report submitted by the Central Pollution Control Board (CPCB) dated 16.11.2020 which reads as follows:

**“REPORT OF CENTRAL POLLUTION CONTROL BOARD (CPCB) AS PER THE DIRECTION OF HONOURABLE NGT (SOUTH ZONE) ORDER DATED JULY 7, 2020 IN THE CASE OFO. A. NO. 123 OF 2017IN THE MATTER OF KRITHIKA GOKULNATH vs. REGISTRAR, ANNA UNIVERSITY AND ORS.**

**1.0 Preamble**

The National Green Tribunal (NGT) Southern Zone, Chennai in the matter of O. A. No. 123 of 2017 in case of Krithika Gokulnath vs. Registrar, Anna University & Ors. has passed an order dated July 7, 2020 and the operative portion of the order is reproduced as under and the copy of the NGT order is annexed as **Annexure 1**:

“We direct the Regional Office, Central Pollution Control Board, Chennai to inspect the institutions mentioned in the application and submit an independent inspection and action taken report in respect of compliance/ violations committed by the institutions in respect of the implementation of Bio Medical Waste Management Rules, 2016 and also the guidelines issued by the 6<sup>th</sup> respondent department regarding scientific disposal of bio medical waste generated in Research/Educational Institutions dealing with DNA analysis. If there is any deficiency found, they are directed to take action against that person in accordance with law in consultation with the respective State Pollution Control Board and also the Pollution Control Committee.

The Regional Office, Central Pollution Control Board is also directed to consider the feasibility of implementing the suggestions of best practices submitted by the applicant to this Tribunal and submit their views on the same to this Tribunal.”

**2.0 Inspection of Universities**

As per the directions, two universities namely Anna University, Chennai, Tamil Nadu and Pondicherry University,

*Kalapet, Puducherry are to be inspected in respect of any violation committed in implementation of Bio-Medical Waste Management (BWM) Rules, 2016. CPCB prepared the questionnaire for obtaining the information from the universities. Anna university was inspected on November 4, 2020 and Pondicherry university was inspected on November 5, 2020. The observations made w.r.t. implementation of BWM Rules, 2016 in universities are depicted in following paragraphs.*

### **2.1 Anna University**

*Anna University is established in the year 1978; however the department of biotechnology was established in the year 1993. It was informed that the Department of Biotechnology research campus located at Taramani is the only department involved in biology/biotechnology research and is the only department generating the Bio-medical Waste (BMW) or biotechnological research waste considered as BMW. Department of Biotechnology has research laboratories exclusive for Bioprocess, Cell signalling, Stem cells, Food process engineering, Proteomics and Genomics, Metabolomics (aging & metabolic disorders).*

*The Department has a large ensemble of instruments such as Bioreactors/ fermentors, High Performance Liquid Chromatography (HPLC), Flow cytometer, confocal microscope, MALDI-TOF mass spectrometry, gel electrophoresis apparatus for proteomics/ genomics, Gel documentation systems, Biosafety cabinets/Laminar flow and various incubators. Research activities involving the above instruments/ apparatus invariably results in some chemical/ biotechnological wastes which needs to be disposed off properly. Proteomics/ genomic studies use gel electrophoresis and several toxic chemicals like polyacrilamide, ethidium bromide, several dyes are used in the preparation of gel. According to the relevant website, other major research instruments in the Dept. of Biotechnology are plate scintillation counter, various liquid handling system, gel documentation system, deep freezers, FPLC, HPLC, ultracentrifuge, refrigerated centrifuges, fluorescence spectrophotometer, freeze-dryer, fermenters, CO<sub>2</sub> incubator, fluorescence &*

absorbance ELISA reader, liquid chromatography, animal cell culture reactor, sonicator and animal house for test animals.

Bioprocess, proteomics and genomic research are generally considered to produce biotechnological research wastes such as spent microbiological media, spent bioprocess liquid, spent protein and DNA/ protein gels containing toxic chemicals and other chemicals used for various purposes. Animal house wastes management and disposal of experiment animals are also very critical. Anna University also have University Innovation Cluster and all the major biomedical/ biotechnological/ bioprocess research facilities are made available. However, there is no information in the website on the waste management aspect of the biotechnological/ biomedical waste.

## **2.2 Observations**

- i. On the day of inspection, university means department of biotechnology at Taramani campus was not fully functional and was working with minimum faculty. It was informed that research activities / academic classes are not carried out in a full fledge manner due to prevailing COVID-19 pandemic situation. The classes are conducted through online and only 30 research scholars out of 50 are attending the classes and doing research activities.
- ii. Department of Biotechnology has obtained authorisation in the name of M/s SPIC BIOPROCESS LABORATORY, Taramani Campus, Chennai. M/s SPIC BIOPROCESS LABORATORY has one time Authorisation from Tamil Nadu Pollution Control Board (TNPCB) under sub-rule 1 of Rule 10 of Bio-Medical Waste Management Rules, 2016 on March 19, 2020. However, M/s. SPIC BIOPROCESS LABORATORY is associated with the University Innovation Cluster supported/ funded by Biotechnology Innovation Research and Assistance Council (BIRAC) and not with the Dept. of Biotechnology. It is presumed that the authorization is for this externally funded project institution and it is not for the university departments generating biotechnological research waste. The copy of the authorisation is annexed as **Annexure 2**.
- iii. According to Authorisation, M/s SPIC BIOPROCESS LABORATORY is permitted to handle chemical solid waste of

0.2 kg/day and Microbiology, biotechnology and other clinical laboratory waste of 2.5 kg/day. The Bio Medical Waste (BMW) generated from the laboratories has to be segregated and stored in yellow colour bags/bins.

- iv. As per the Schedule-I of BMW Management Rules, 2016; the department is segregating the waste in three bins viz. Red, Blue & Yellow bins. These bins are placed in each research laboratory for collection of BMW.
- v. However the authorisation issued by the TNPCB is only for yellow category of waste, but as per the manifest copy given by M/s G.J. Autoclave is for yellow, red, blue and white category of BMW. TNPCB may once again review the category of waste generated by Anna university as per the schedule I of the BWM Rules, 2016 and issue the authorisation accordingly.
- vi. The petri dish used for the cell culture, DNA recombinant stem cell are disposed in the yellow colour bins whereas the gloves, mask are disposed in red colour bins. The general waste such as plastic, food waste, plastic containers are disposed in green bins. However, no information provided regarding disposal of protein/ DNA gels containing toxic chemicals.
- vii. M/s SPIC BIOPROCESS LABORATORY has entered into MoU with M/s G.J. Multiclave (India) Pvt. Ltd., Chennai in the November 1, 2017 to March, 2019. The agreement was renewed on April 10, 2019 and valid up to March 31, 2021 for the disposal of BMW through incineration.
- viii. It was informed that the petri dish, vials, beaker, pipette used for cell culture of DNA is a sterilized plastic material and after the analysis it is disposed in yellow colour bins. The waste collected is pre-treated / disinfected in autoclave before giving to G. J. Autoclave for final disposal through incineration.
- ix. It was informed that around 10 kg/month of biotechnology waste and 0.2-0.5 kg/month chemical waste is generated. The university has not maintained any records for the generation of the BMW to verify the actual quantity. The BMW generated is handled by individual research scholars and no dedicated person is identified for collection and pre-treatment.
- x. The Department of Biotechnology has one type autoclave of capacity 2.1 kg/cycle and the BMW generated is pre-treated in autoclave. It was informed that, temperature of 120° C and 13

*psi pressure is maintained and residence time of 14-20 minutes is given for disinfecting the waste. However, it should be operated to ensure temperature of more than 121° C and 15 psi pressure with disinfection time of 30 to 40 minutes and no records maintained on the disinfection to verify the operating condition of autoclave.*

- xi. During inspection, sufficient waste was not accumulated to verify the operating condition of the autoclave. The university claims that the validation test is done once in a week using streaking as say to ensure that autoclave is done properly. However, disinfection efficacy or validation of autoclave has to be done using standard spore test and again no record maintained in this regard.*
- xii. This clearly indicates that the university is not operating the autoclave as per the Schedule II of the BWM Rules, 2016. The validation test for autoclave is also not carried as per the Schedule II of the BWM Rules, 2016.*
- xiii. The university informed that most of the experiments in biology /biotechnology departments do not involve harsh or hazardous reagents as used in chemistry laboratory and most assays are carried out in disposal plastic wares, the washing liquid possibly contains diluted detergents or bleach and that itself is considered as a method of disinfection and no additional strategies are followed. Hence the liquid waste generated in the laboratory and the sewage from the department is channelized to the septic tank followed by soak pit. However, this statement is vague and misleading as it is well known that toxic carcinogenic chemicals are frequently used in many biotechnological manipulations. For example, the chemical Ethidium bromide a widely used DNA binding fluorescent dye used in agarose gel electrophorus is applications which are a basic molecular biology manipulation in all biotechnology labs employing DNA amplification. Ethidium bromide is a known mutagen with proven carcinogenicity.*
- xiv. The biotechnology department has provided a space in the 1<sup>st</sup> floor between the laboratories as a central storage area for autoclave and to store the treated BMW. The area is accessible to all and is not in lock & key manner.*

- xv. It was informed that, before the agreement with M/s G.J. Multiclave (in November, 2017), the BMW generated by the department was disposed in deep burial pit located inside the campus. At present the pit is closed with concrete and sealed, during inspection it was verified.

### **2.3 Pondicherry University**

Pondicherry University was established in the year 1985. The University has 15 Schools, 39 Departments, 9 Centres and it was informed that the School of Life Sciences (Centre for Bioinformatics, Departments of Bio-chemistry & Molecular Biology, Biotechnology, Ecology & Environment Sciences, Food Science & Technology, Microbiology); Madanjeet School of Green Energy Technologies having Centre for Green Energy Technology and Nano Sciences & Technology; School of Engineering & Technology having centre for pollution control & environmental engineering; School of Physical, Chemical & Applied Sciences (Departments of Chemistry, Earth Sciences & Physics) are the source of biotechnological/ chemical research waste generation/BMW. Every school/ department has specific research programs and research project specific laboratories.

The Department of biotechnology has four well-equipped laboratories with all modern facilities for Plant tissue culture, Animal cell culture, Biosafety facility and Microscopy & Photo documentation facility. These laboratories have instruments such as High speed refrigerated centrifuges, UV-Vis spectrophotometer, Bioreactor system, Fermentor, CO<sub>2</sub> incubator, CO<sub>2</sub> -O<sub>2</sub> Incubator, Electrophoresis apparatus, Electroporator, Gel apparatus, Gel documentation and chemiluminescent system, ELISA reader, Multimode reader, PCR, Real-time PCR, Flash Chromatography, HPLC, GC, LCMS, Vacuum concentrator, TG and 2D Electrophoresis (IEF), Flow cytometer, Lyophilizer and Phase contrast, Luminometer, MACS (Magnetic Active Cell Sorter) Phase contrast, Fluorescence and inverted microscopes, -80o C deep freezers, Ultrasonicator, Luminescence Spectrometer and Microplate Spectro fluorimeter.

Every school/ department has specific research programs and research project specific laboratories. Some of

*the research projects carried out at the university are Synthesis, identification and isolation of chemicals/ compounds/ molecules for chemical/ biological activity, Development of green energy technologies, Drug discovery and development from natural products, Synthesis and characterization of nano particles/ nano materials for various purposes, Identification of various pollutants - chemical/ biological nature, Effects of toxins on human and environment, Small molecule and novel-materials synthesis, Development of novel pharmaceuticals and therapeutics, Innovative healthcare solutions, Chemical biology , Microbial Cultures etc.*

#### **2.4 Observations**

- i. On the day of inspection (November 5, 2020), the university was not fully operational, many departments were closed. It was informed that due to the COVID-19 pandemic situation, classes for Post Graduate students are conducted through online. It was also informed that from October 15, 2020 onwards, about 30 research scholars are doing the research activity and each laboratory is being utilized by average of 3-4 students per day.*
- ii. Pondicherry University, Kalapet, Puducherry has obtained one time Authorisation from Puducherry Pollution Control Committee (PPCC) under sub -rule 1 of Rule 10 of Bio-Medical Waste Management Rules, 2016 on June 19, 2020. The copy of the authorisation is attached as **Annexure 3**.*
- iii. Pondicherry University is authorised for generation, segregation, collection, storage and disposal of yellow category waste of 6 kg/day, 2 kg/day of red category waste, 0.5 kg/day of white category and 0.5 kg/day of blue category waste.*
- iv. Pondicherry University has entered into MoU with M/s Pondicherry Solid Waste Management Company Pvt. Ltd., Thuthipet, Puducherry on March 17, 2020 valid up to March 16, 2021 for the disposal of BMW generated from four schools through incineration.*
- v. During visit to Biotechnology department it was noticed that, in one of the cell culture laboratory there was no colour coded bins for disposing the waste. The waste was not segregated and disposed together in one bin. (Photograph no. 2)*

- vi. *There was no display of poster for disposing different category of waste in all the four laboratories. No records have been maintained for the generation of BMW to quantify.*
- vii. *One dedicated person has been identified for the disinfecting or treating the bio-medical waste. The generated from the laboratories is collected and disinfected.*
- viii. *During inspection, it was informed that the metal rack outside the autoclave room is used as an area for storing the BMW before treatment. The autoclave used for disinfecting is kept along with the other two autoclave used for sterilization. (Photograph no. 2)*
- ix. *The department of biotechnology has one vacuum type autoclave of capacity 150 litres of Technico make. During inspection, the autoclave was operating with a temperature of 105°C, pressure of 12 psi with residence time of 14 minutes. This indicates that the autoclave is not used for decontamination.*
- x. *As per the Schedule II of BWM, Rules 2016 the vacuum type autoclave, the waste should be subjected to the following conditions;*
- *a temperature of not less than 121°C and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or*
  - *a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;*
- xi. *This clearly indicates that the department is not disinfecting the waste according to the conditions mentioned in the schedule II of the BWM, Rules 2016. The log book for operating the autoclave is not maintained.*
- xii. *It was informed that spore test for the validation of autoclave is conducted every year, but according to the schedule II of BWM Rules, 2016, every week the test has to be conducted to ensure that the autoclave is carried out effectively. The records of the validation test have to be maintained for atleast five years.*
- xiii. *The treated waste is stored in a room along with other materials and has no dedicated storage facility/area.*

- xiv. The university till today has not sent the waste to M/s Pondicherry Solid Waste Management Company Pvt. Ltd., it was informed that after obtaining the authorisation, the nationwide lockdown was imposed and due to prevailing COVID -19 pandemic situation, the departments were not operational.
- xv. However few quantity of wastes generated is disposed of in a deep burial pit after disinfection.
- xvi. In the other departments/laboratories where BMW/ biotechnological research waste are generated, there is no practise of segregation, storage and disinfection as per the BWM, Rules 2016.

### **3.0 Views on best practises submitted by the applicant.**

The applicant in the suggestions for the best practises to be adopted for the DNA recombinant research waste issued by the Department of Biotechnology (DBT), Ministry of Science and Technology, GoI was reviewed. The guidelines titled “Regulations and Guidelines for Recombinant DNA Research and Bio containment, 2017” is applicable for research, development and handling of genetically engineer organisms and non-genetically engineered hazardous microorganisms. The regulations 2.3.5 titled decontamination and disposal is par with the CPCB Guidelines for Management of Healthcare Waste as per Biomedical Waste Management Rules, 2016. In the regulation, after the regulation 2.3.5, DBT has mentioned that **Selection of appropriate decontamination and disinfection strategies for biomedical waste treatment and disposal facilities should be in accordance to those mentioned in the “Revised Guidelines for Common Bio-medical Waste Treatment and Disposal Facilities”(2016) developed by Central Pollution Control Board (CPCB).**

During inspection, the Anna & Pondicherry universities informed that, the department of Biotechnology has an Institutional Biosafety Committee (IBSC) and reviews the day to day activity related to biotechnology research projects. The regulation and guidelines for Recombinant DNA Research and Biocontainment, 2017 is adopted and practised. However there are no indications that the universities followed the

regulations issued by DBT in Decontamination and disposal of biotechnological research wastes.

The applicant has suggested the best practices document by the National Research Council of the National Academics, Washington DC titled “Prudent Practices in Chemical Laboratory – Handling and Management of Chemical Hazards” This document prescribes the guidelines for collection, storage and disposal of Hazardous, radioactive, biology hazards and chemical waste generated by the chemical laboratories in an research/educational institutes. These best practices may be adopted by the universities/ research laboratories for safe disposal of chemical, hazardous and radioactive wastes.

#### **4.0 Suggestions and Recommendations**

- i. The universities have to strictly follow the “Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017” and Bio Medical Waste Management Rules, 2016 for handling, decontamination and disposal of the Bio Medical Waste generated from the departments.
- ii. Anna university has obtained one time authorisation from TNPCB for the M/s SPIC BIOPROCESS LABORATORY, Taramani Campus, Chennai. The university has to identify the departments generating the Bio Medical Waste and authorisation has to be obtained.
- iii. While obtaining the authorisation, the universities have to identify the category of waste generated from each department and clearly mention in the application.
- iv. In case of M/s SPIC BIOPROCESS LABORATORY, authorisation is issued only for the yellow category of waste, whereas the red, yellow, blue and white category of waste is disposed to the M/s G. J. Multiclave Pvt. Ltd.,
- v. TNPCB may once again review the category of waste generated by Anna university as per the schedule I of the BWM Rules, 2016 and accordingly authorisation may be issued.
- vi. The universities generating the BMW have to install a small weighing machine to quantify the waste generated from each laboratory/departments and recorded. So that the exact

- quantity of BMW generated, treated & disposed shall be submitted to SPCBs/PCCs in the Annual report.
- vii. The universities have to maintain log book/ records for the segregation, collection, treatment and disposal of BMW. The records maintained should be made available for the monitoring team.
  - viii. Treatment of BMW through autoclave should be followed according to the schedule II of the BWM, Rules 2016. The validation test should be done every week to ensure that the waste is disinfected effectively and as per the methods mentioned in schedule II of the BWM, Rules 2016.
  - ix. The universities shall identify one dedicated person responsible for segregation, collection, treatment and disposal of BMW. The concerned person responsible should be trained accordingly to manage & handle the BMW efficiently.
  - x. As per the Bio Medical Waste Management Rules, 2016, it is mandatory that all the employees, staff and students need to be trained to handle & manage the BWM.
  - xi. A designated central storage room shall be identified within the premises for storage of bio-medical waste, till the waste is treated and disposed to Common Biomedical Waste Treatment Facility. The room should be under the responsibility of a designated person and should be under lock & key.
  - xii. Pondicherry University to stop using the deep burial pit for disposing the BMW and send the treated waste to the CBMTF as per the authorization.
  - xiii. Most of the biotechnological waste generation is from externally funded projects funded by various Govt. funding agencies. However, funding essentially support research infrastructure development and currently no emphasis is given on disposal and waste management needed in these funded research projects. It is suggested that the funding agencies should ensure that the institutes being funded by them have proper waste disposal/ management facilities (Proper waste disposal/ management facilities shall be made mandatory for getting research grants/ funds) and adequate portion of grant/ fund shall be earmarked exclusively for the management/ disposal of biotechnological/ research wastes.”

7. It is seen from the report that there were certain deficiencies noted in carrying out the provisions of Biomedical Waste Management Rules, 2016 by the Puducherry University as well as the Anna University. Though, they have mentioned that there are certain violations, being a regulating authority they have not mentioned as to what is the proposed action that they are going to take against those erring units.
8. As per order dated 20.03.2020, this Tribunal had directed the 6<sup>th</sup> respondent to file a detailed status report as to whether any further guidelines have been given as to how the biomedical waste that has been generated by units undertaking DNA research or analysis and as to how such organism are to be destroyed or made harmless before disposal into the environment and also whether any specific scientific method is prescribed for such destruction by the Department of Biotechnology in this regard.
9. When this was pointed out, the learned counsel appearing for the respondents 6 & 7 submitted that if some time is granted, they may be able to come with proper instruction from the departments regarding these aspects.
10. It is also seen from the report submitted by the Central Pollution Control Board (CPCB) that regulations and guidelines for recombinant DNA research and bio-containment, 2017 has

been issued by the Department of Biotechnology which has to be followed by the universities for disposal of such waste generated in their institution. Being a supervisory authority, having found that certain violations have been committed by the research institutes and universities in handling such biomedical waste generated during their research activities in an unscientific manner which is likely to cause environmental degradation, they have not taken any action against those persons who are responsible for the same as well. They are also expected to give proper direction to the universities to follow the guidelines provided by the Biotechnology Department in 2017 and also to obtain necessary authorization and implementation of Biomedical Waste Management Rules, 2016 in its letter and spirit in their institution.

11. If educational institutions themselves are not following the same, how can one expect that the same will be followed by the persons who have been trained by them when they are involved independently in such activities. The educational institutions must be a model for implementing the rules in its letter and spirit and educate the persons who are involving in the same or who are expected to experiment the same in their avocation carrier in future as to how such they will have to be dealt with in a scientific manner imparting the necessity of protecting the

environment as priority commitment as contemplated under Article 51 A(g) of Constitution of India.

12. The Tamil Nadu Pollution Control Board (TNPCB), Puducherry Pollution Control Committee as well as the Central Pollution Control Board (CPCB) are directed to submit a further action taken report on the basis of the observations and conclusions arrived at by them on inspection of these institutions by applying the principle of natural justice by giving an opportunity to the parties before imposing any penal action including imposition of environmental compensation against them.
13. The concerned universities are also directed to submit their independent compliance report regarding the observations made by the Central Pollution Control Board (CPCB) in their report extracted above for implementation of Biomedical Waste Management Rules, 2016 and also the guidelines provided by the Department of Biotechnology, Ministry of Science and Technology, Government of India in this regard before the next hearing date.
14. They are directed to submit their independent response as well as the action taken report as directed on or before 27.01.2021 to this Tribunal by e-filing along with necessary hardcopies to be produced as per Rules.

15. The Registry is directed to communicate this order to the above authorities by e-mail immediately so as to enable to comply with the direction.
16. For consideration of report post on 27.01.2021.

.....J.M.  
(Justice K. Ramakrishnan)

.....E.M.  
(Shri. Saibal Dasgupta)

O.A. No.123/2017  
18<sup>th</sup> November, 2020. Mn.





केन्द्रीय प्रदूषण नियंत्रण बोर्ड  
CENTRAL POLLUTION CONTROL BOARD

पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय, भारत सरकार  
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE, GOVT. OF INDIA

February 12, 2021

Tech/02/legal/RDC/2020-21/-39

To

The Registrar  
Anna University  
Sardar Patel Road  
Guindy, Chennai - 600 025

**Sub: Compliance in the matter of O.A. No. 123 of 2017 titled: Kritika Gokulnath Vs Registrar, Anna University & Ors.**

Ref.: NGT order dated November 18, 2020 and inspection by RD, Chennai on January 20, 2021

Sir,

Hon'ble NGT, Southern Bench, Chennai in the matter of Original Application No. 123/2017 (SZ), passed following directions vide order dated November 18, 2021:

*"..... The Tamil Nadu Pollution Control Board (TNPCB), Puducherry Pollution Control Committee as well as the Central Pollution Control Board (CPCB) are directed to submit a further action taken report on the basis of the observations and conclusions arrived at by them on inspection of these institutions by applying the principle of natural justice by giving an opportunity to the parties before imposing any penal action including imposition of environmental compensation against them...."*

In compliance to aforesaid Order, a team from Regional Directorate, CPCB, Chennai inspected Bio-technology department of Anna University & verified the present status of compliance on January 20, 2021. During inspection it was found that the facility was complying with recommendations of CPCB made in earlier inspections.

In view of above, it is requested to continue complying with BMW Rules 2016 and inform CPCB after resuming full operations to re-assess compliance.

Yours faithfully

**DESPATCHED**

No.: 39  
Date: 12/2/2021  
Signature: G. Ezhilaraj

*H. D. Varalaxmi*  
(H D Varalaxmi)  
Regional Director

क्षेत्रीय निदेशालय (चेन्नई) : द्वितीय तल, 77-ए, साउथ एवेन्यू रोड, अंबतूर औद्योगिक क्षेत्र, अंबतूर तालुक, तिरुवल्लूर जिला, चेन्नई - ६०००५८

Regional Directorate (Chennai) : Second Floor, 77-A, South Avenue Road, Ambattur Industrial Estate, Ambattur Taluk, Thiruvallur District, Chennai - 600 058. Mobile : 9143310614, 9143307374, Email : cpcbrcchennai@gmail.com

प्रधान कार्यालय : परिवेश भवन, पूर्वी अर्जुन नगर, दिल्ली- ११० ०३२.

Head Office : Parivesh Bhawan, East Arjun Nagar, Delhi - 110 032.

दूरभाष / Telephone : 011-43102030, Fax : 22305793, 22307078, 22307079, 22301932, 22304948

ई-मेल / E-mail : cpcb@nic.in वेबसाइट / Website : www.cpcb.nic.in



केन्द्रीय प्रदूषण नियंत्रण बोर्ड  
CENTRAL POLLUTION CONTROL BOARD

पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय, भारत सरकार  
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE, GOVT. OF INDIA

February 12 2021

Tech/02/legal/RDC/2020-21/-40

To

The Registrar  
Pondicherry University  
R. Venkataraman Nagar  
Kalapet  
Puducherry - 605 014

DESPATCHED

No.: 40  
Date: 12/2/21  
Signature: G. Eshwara

**Sub: Compliance in the matter of O.A. No. 123 of 2017 titled: Kritika Gokulnath Vs Registrar, Anna University & Ors.**

**Ref.: NGT order dated November 18, 2020 and inspection by RD, Chennai on January 21, 2021**

Sir,

Hon'ble NGT, Southern Bench, Chennai in the matter of Original Application No. 123/2017 (SZ), passed following directions vide order dated November 18, 2021:

"..... The Tamil Nadu Pollution Control Board (TNPCB), Puducherry Pollution Control Committee as well as the Central Pollution Control Board (CPCB) are directed to submit a further action taken report on the basis of the observations and conclusions arrived at by them on inspection of these institutions by applying the principle of natural justice by giving an opportunity to the parties before imposing any penal action including imposition of environmental compensation against them...."

In compliance to aforesaid Order, a team from Regional Directorate, CPCB, Chennai inspected Puducherry university & verified the status of compliance on January 21, 2021. As per inspection report, Puducherry University was complying with recommendations of CPCB except for the following point:

- Completing construction of designated central storage room within the premises, preferably away from main building, for temporary storage of bio-medical waste, till the waste is collected by Common Biomedical Waste Treatment Facility. The room is required to be constructed as per CPCB guidelines.

क्षेत्रीय निदेशालय (चेन्नई) : द्वितीय तल, 77-ए, साउथ एवेन्यू रोड, अंबतूर औद्योगिक क्षेत्र, अंबतूर तालुक, तिरुवल्लूर जिला, चेन्नई - ६०००५८  
Regional Directorate (Chennai) : Second Floor, 77-A, South Avenue Road, Ambattur Industrial Estate, Ambattur Taluk, Thiruvallur District, Chennai - 600 058. Mobile : 9445019014, 8745057014, Email : cpcbrcchennai@gmail.com

प्रधान कार्यालय : परिवेश भवन, पूर्वी अर्जुन नगर, दिल्ली- ११० ०३२.

Head Office : Parivesh Bhawan, East Arjun Nagar, Delhi - 110 032.

दूरभाष / Telephone : 011-43102030, Fax : 22305793, 22307078, 22307079, 22304948

ई-मेल / E-mail : cpcb@nic.in वेबसाइट / Website : www.cpcb.nic.in

-2-

In view of above, it is requested to complete construction of storage room and continue to ensure compliance with BMW Rules 2016. You are also requested to inform CPCB after resuming full operations to re-assess compliance.

Yours faithfully



(H D Varalaxmi)  
Regional Director



## TAMILNADU POLLUTION CONTROL BOARD

### FORM III

(See Rule 10)

**AUTHORISATION No: 20BAD2443 Dated: 05.01.2021**

**Proceeding No: TNPCB/F.002443/BWA/OS/CHN/2020 Dated:05 .01.2021**

**Sub:** Tamil Nadu Pollution Control Board - Bio-Medical Waste Authorization - One Time Authorization -HCF - M/s. SPIC BIOPROCESS LABORATORY, TARAMANI CAMPUS, CSIR ROAD, CHENNAI - 600 113 - Authorization under Rule 10 of the Bio-Medical Waste Management Rules, 2016 enacted under Environment (Protection) Act, 1986 - Issued- Reg.

**Ref:** 1. Unit's application No.002443 dated: 22.12.2020 for Authorization.  
2. BMW-IR. No: F.002443 /BWA/OS/CHN/2020 Dated: 05.01.2021.

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### AUTHORISATION FOR OPERATING A FACILITY FOR GENERATION, COLLECTION, RECEPTION, TREATMENT, STORAGE, TRANSPORT AND DISPOSAL OF BIO-MEDICAL WASTES

1. File number of authorization: 20BAD2443 and date of issue 05.01.2021.
2. The Proprietor of M/s. SPIC BIOPROCESS LABORATORY, TARAMANI CAMPUS, CSIR ROAD, CHENNAI - 600 113 is hereby granted an Authorization for Generation, Segregation, Collection, Storage, Packaging, Disposal of Bio-Medical Waste
3. M/s. SPIC BIOPROCESS LABORATORY is hereby authorized for handling of Bio-Medical waste as per the capacity given below.

i)	Number of beds of HCF	Non Bedded	Nos	
ii)	Quantity of Bio-Medical Waste handled, treated or disposed			
	<b>Category</b>	<b>Type of Waste</b>	<b>Quantity permitted for handling</b>	<b>Unit</b>
	Yellow	a) Human Anatomical Waste	0	-
		b) Animal Anatomical Waste	0.05	Kg/day
		c) Soiled Waste	0	-
		d) Expired or Discarded Medicines	0	-
		e) Chemical Solid Waste	0.2	Kg/day
		f) Chemical Liquid Waste in KLD	0.0025	KLD
		g) Discarded linen; mattresses, beddings contaminated with blood or body fluid	0	-
		h) Microbiology, Biotechnology and other clinical laboratory waste	2.5	Kg/day

*Biosafety  
file  
B2*

**POLLUTION PREVENTION PAYS**



Category	Type of Waste	Quantity permitted for handling	Unit
Red	Contaminated waste (Recyclable)	0.2	Kg/day
White(Translucent)	Waste sharps including Metals	0.1	Kg/day
Blue	Glassware	0.1	Kg/day
	Glassware Metallic Body	0	-

- 4 This one time authorization is valid for the non-bedded Health Care facility only.
- 5 The authorization is issued subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

*R. Maniyarasu*  
District Environmental Engineer

*Pm*  
5/11/2021  
Tamil Nadu Pollution Control Board  
Chennai

#### TERMS AND CONDITIONS OF AUTHORIZATION

- The authorization shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
- The authorization or its renewal shall be produced for inspection at the request of an officer authorized by the Tamil Nadu State Pollution Control Board.
- The person authorized shall not rent, lend, sell, transfer or otherwise transport the Bio-Medical wastes without obtaining prior permission of Tamil Nadu State Pollution Control Board.
- Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.
- It is the duty of the authorized person to take prior permission of the Tamil Nadu Pollution Control Board to close down the facility and such other terms and conditions may be stipulated by Tamil Nadu Pollution Control Board.
- Any other conditions for compliance as per the Guidelines issued by the MoEF&CC or CPCB from time to time.

#### ADDITIONAL CONDITIONS

- The unit shall comply with the provisions of the Bio Medical Waste Management Rules, 2016.
- The unit shall dispose the bio medical waste then and there to the CBMWTDF and maintain proper records.
- The Health Care Facility shall ensure that No beds are provided in the clinic in future.

**POLLUTION PREVENTION PAYS**



## TAMILNADU POLLUTION CONTROL BOARD

### SPECIAL CONDITIONS - HCF

1	All the provisions of the Bio-Medical Waste Management Rules, 2016 must be complied with.
2	The HCF shall take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with the Bio-Medical Waste (BMW) Management Rules, 2016.
3	The HCF shall make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I of the BMW Rules, 2016. It shall be ensured that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I of the BMW Management Rules, 2016.
4	The HCF shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDS Control Organization (NACO) guidelines and sent to the common bio-medical waste treatment facility for final disposal.
5	The HCF shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of Notification of the BMW Management Rules, 2016.
6	The HCF shall dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time.
7	The HCF shall not give treated bio-medical waste with municipal solid waste.
8	The HCF shall establish a Bar-Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the Notification of the BMW Management Rules, 2016.
9	The HCF shall ensure segregation of liquid chemical waste at source and also ensure pre-treatment or neutralization prior to mixing with other effluent generated from health care facilities.
10	The HCF shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974).
11	The HCF shall maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I of the BMW Management Rules, 2016.
12	The HCF shall inform to TNPCB immediately in case the operator of a CBMWTF does not collect the bio-medical waste within the intended time or as per the agreed time.
13	The HCF shall establish a system to review and monitor the activities related to bio-medical waste management by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of the committee shall be submitted along with the annual report to the prescribed authority.
14	It is the responsibility of the occupier of the HCF that the only segregated bio-medical waste as per the Schedule-I of the BMW Management Rules, 2016 shall be handed over to common bio-medical waste treatment facility for treatment, processing and final disposal.
15	It shall be ensured that no untreated bio-medical waste shall be mixed with other wastes.
16	The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I of the BMW Management Rules, 2016 prior to its storage, transportation, treatment and disposal.
17	The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV of the BMW Management Rules, 2016. The bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.

**POLLUTION PREVENTION PAYS**

18	Untreated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not be stored beyond a period of forty-eight hours: Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and in accordance with the standards for doing so.
19	Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
20	Cytotoxic drug vials shall not be handed over to unauthorized person under any circumstances. These shall be sent back to the manufacturer for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature >1200C.
21	Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
22	On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization and then given to the common bio-medical waste treatment and disposal facility.
23	Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage.
24	The HCF shall maintain records related to the generation, collection, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste.
25	The HCF shall submit an Annual Report to the prescribed authority (TNPCB) in Form-IV, on or before the 30th June of every year for the period from January to December of the preceding year.
26	The HCF shall make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of Notification of the BMW Management Rules, 2016.
27	In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorization was earlier granted, the occupier or operator of HCF shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of Authorization.
28	In case of any major accident at any institution of HCF facility or any other site while handling bio- medical waste, the authorized person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.
29	The HCF shall ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments.
30	The occupier of the HCF or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio- medical wastes. The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.

**POLLUTION PREVENTION PAYS**



## TAMILNADU POLLUTION CONTROL BOARD

- 31 The HCF shall adopt the following treatment and disposal methods as described in the BMW Management Rules, 2016
- i. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms as given in Schedule- III.
  - ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.

*R. Manigandan*  
 District Environmental Engineer  
 Tamil Nadu Pollution Control Board  
 Chennai

*5/1/2024*

To  
 The Head,

M/s. SPIC BIOPROCESS LABORATORY,  
 DEPARTMENT OF BIOTECHNOLOGY,  
 ANNA UNIVERSITY,  
 CHENNAI – 600 113

Copy submitted to:

1. The Member Secretary, Tamil Nadu Pollution Control Board, Chennai for favour of kind information.
2. The JCEE-Monitoring, Tamil Nadu Pollution Control Board, Chennai for favour of kind information.

**POLLUTION PREVENTION PAYS**





Sl. No	Date	Weight (in g / Kg)	Waste Category Red/Blue/Yellow	Pre-treatment Yes / No	Lab source	Signature
1.	25/12/2020	300g	Red	Yes (Hoc / spray)	Bioprocess	D. Kamatchi
2	29/12/2020	0.225 kg	Red	Yes (Alcohol sp)	Mol. Bio	S. Vignesh
3.	04/01/2021	3.5 kg 1.0 kg	yellow Red	yes (Hoc spray) yes "	Bio process "	D. Kamatchi
4.	08/01/2021	2.5 kg 1.0 kg	yellow Red	yes (Hoc)	mol. Bio lab	R. S. Anand
5.	11/01/2021	2.0 kg	Yellow	Yes (Hoc)	Bio process	R. S. Anand
6.	19/01/2021	0.1 kg	Yellow	Yes	Mol. Bio Lab	D. Kamatchi
* 7	20/01/2021	0.450 kg 0.375 kg	Red Yellow	Yes (Hoc) Yes (Hoc)	M. Bio Lab	R. S. Anand

# HOSPITAL COPY

## G.J. Multi Clave (India) Pvt. Ltd.,

New No.37, Old No.20, Teachers Colony, Kamarajar Avenue,  
Adyar, Chennai - 600 020. Ph : 044 - 2445 1683

No. **64609** Veh.No. **8352**  
Date : **20/01/21** Time : .....

### B.M.W. COLLECTION SLIP

- 1. HCE Name : **Head of the Department**
- 2. Collected By : **V. Saravanan**
- 3. Collected from : **Saravanan**
- a. Red : **2:000**
- b. Yellow : **6:000**
- C. White / Sharp Containers : .....
- d. Blue : .....
- 4. Total Bags / Kg : **8:000**
- 5. Waste Segregated : Yes  No
- 6. Barcoded Bags : Yes  No
- 7. Bags Sealed / Tied Properly : Yes  No

For GJM (I) P. Ltd **[Signature]**

**[Signature]** For HCE